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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from _____ to _____

Commission File Number 001-33038

Alaunos Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**84-1475642** **(IRS Employer Identification No.)**
8030 El Rio Street **Houston, TX** **(Address of Principal Executive Offices)**	**77054** **(Zip Code)**

(346) 355-4099
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	**TCRT**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerate filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer	☐	Accelerated Filer	☐
Non- Accelerated Filer	☑	Smaller Reporting Company	☑
		Emerging Growth Company	☐

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates was $221,548,093 as of June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 178,667,817 shares of common stock held by non-affiliates and a closing price of $1.24 as reported on the Nasdaq Global Select on June 30, 2022. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors or 10% beneficial owners are, in fact, affiliates of the registrant.

As of March 2, 2023, there were 240,627,055 shares of the registrant's common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

Alaunos Therapeutics, Inc.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are all statements contained in this Annual Report that are not historical fact, and in some cases can be identified by terms such as: "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "project," "target," "will" and other words and terms of similar meaning.

These statements are based on management's current beliefs and assumptions and on information currently available to management. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- our ability to raise substantial additional capital to continue as a going concern, fund our planned operations and repay our existing indebtedness;
- estimates regarding our expenses, use of cash, timing of future cash needs and anticipated capital requirements;
- the development of our product candidates, including statements regarding the initiation, timing, progress and results of our research and development, preclinical studies and clinical programs;
- our ability to advance our product candidates through various stages of development, especially through pivotal safety and efficacy trials;
- the risk that final trial data may not support interim analysis of the viability of our product candidates;
- our expectation regarding the safety and efficacy of our product candidates;
- the timing, scope or likelihood of regulatory filings and approvals from the U.S. Food and Drug Administration, or FDA, or equivalent foreign regulatory agencies for our product candidates and for which indications;
- our ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreements;
- our ability to enter into partnerships or strategic collaboration agreements and our ability to achieve the results and potential benefits contemplated from relationships with collaborators;
- our ability to maintain and establish collaborations and licenses;
- our expectation of developments and projections relating to competition from other pharmaceutical and biotechnology companies or our industry;
- our estimates regarding the potential market opportunity for our product candidates;
- the anticipated rate and degree of commercial scope and potential, as well as market acceptance of our product candidates for any indication, if approved;
- the anticipated amount, timing and accounting of contract liabilities, milestones and other payments under licensing, collaboration or acquisition agreements, research and development costs and other expenses;
- our intellectual property position, including the strength and enforceability of our intellectual property rights;
- our ability to attract and retain qualified employees and key personnel; and
- the impact on our business from a pandemic, epidemic or outbreak, including the COVID-19 pandemic.

Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context requires otherwise, references in this Annual Report to "Alaunos," the "Company," "we," "us" or "our" refer to Alaunos Therapeutics, Inc., and its subsidiaries.

We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. We own the trademarks Alaunos™, Ziopharm® and hunTR® as well as the graphic trademark found on our website. Other trademarks, service marks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Annual Report on Form 10-K are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

SUMMARY OF SELECTED RISKS ASSOCIATED WITH OUR BUSINESS

Our business faces significant risks and uncertainties. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors" in Part I, Item 1A of this Annual Report. Some of the more significant risks include the following:

- We will require substantial additional financial resources to continue as a going concern, continue ongoing development of our product candidates and pursue our business objectives; if we are unable to obtain these additional resources when needed, we may be forced to delay or discontinue our planned operations, including clinical testing of our product candidates.
- Our plans to develop and commercialize non-viral adoptive cellular therapies based on T-cell receptor, or TCR, therapies can be considered as new approaches to cancer treatment, the successful development of which is subject to significant challenges.
- Our current product candidates are based on novel technologies and are supported by limited clinical data and we cannot assure you that our current and planned clinical trials will produce data that supports regulatory approval of one or more of these product candidates.
- We will need to attract, recruit and hire qualified personnel and we will continue to rely on key scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.
- Our existing indebtedness, together with our other financial obligations and contractual commitments, could adversely affect our financial condition and restrict our future operations. For instance, we were required to deposit a significant amount of cash into an account to be held as collateral.
- If we are unable to obtain the necessary United States or worldwide regulatory approvals to commercialize any product candidate, our business will suffer.
- Our product candidates are in various stages of clinical development, which is very expensive and time-consuming. We cannot be certain when we will be able to submit a Biologics License Application, or BLA, to the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business.
- Our cellular immuno-oncology product candidates rely on the availability of reagents, specialized equipment and other specialty materials and infrastructure, 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.
- If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.
- Our immuno-oncology product candidates may face competition in the future from biosimilars.
- If we or our licensors fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish and our ability to successfully commercialize our products may be impaired.
- Our stock price has been, and may continue to be, volatile.

PART I

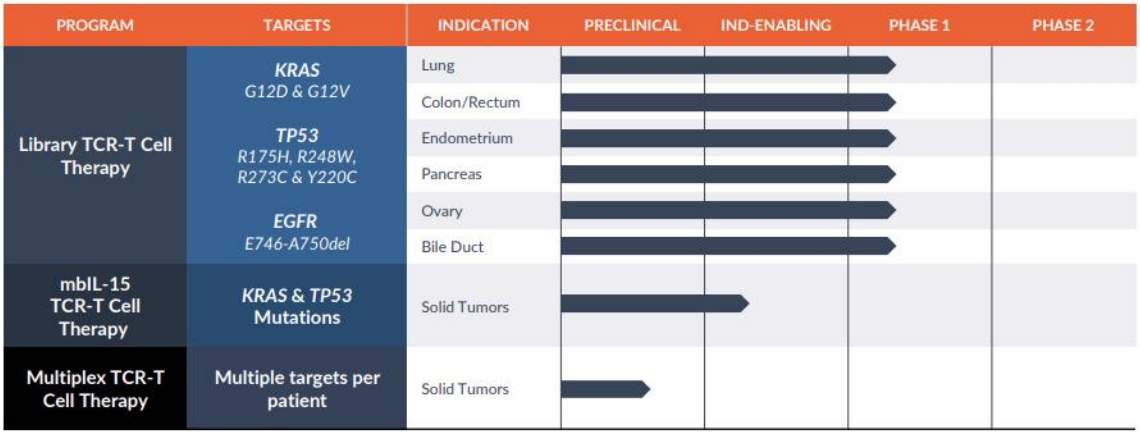
Item 1. Business

Overview

We are a clinical-stage oncology-focused cell therapy company developing adoptive TCR engineered T-cell therapies, or TCR-T, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. We are leveraging our cancer hotspot mutation TCR library and our proprietary, non-viral *Sleeping Beauty* gene transfer platform to design and manufacture patient-specific cell therapies that target neoantigens arising from common tumor-related mutations in key oncogenic genes, including *KRAS*, *TP53* and *EGFR*. In collaboration with The University of Texas MD Anderson Cancer Center, or MD Anderson, we are currently enrolling patients for a Phase 1/2 clinical trial evaluating 12 TCRs reactive to mutated *KRAS*, *TP53* and *EGFR* from our TCR library for the investigational treatment of non-small cell lung, colorectal, endometrial, pancreatic, ovarian and bile duct cancers, which we refer to as our TCR-T Library Phase 1/2 Trial.

In the United States, solid tumors represent approximately 90% of new cancer diagnoses. Approximately 2.0 million people are expected to be diagnosed with cancer in the United States in 2023 and approximately 610,000 people are expected to die from cancer in the United States in 2023. Some of the cancers we are targeting in our TCR-T Library Phase 1/2 Trial are expected to be among the most prevalent cancers diagnosed in the United States in 2023. In 2023, it is estimated that 238,340 people will be diagnosed with lung and bronchus cancer, 153,020 will be diagnosed with colorectal cancer, 66,200 people will be diagnosed with endometrial cancer, 64,050 people will be diagnosed with pancreatic cancer, 19,710 people will be diagnosed with ovarian cancer and approximately 8,000 people will be diagnosed with bile duct cancer. Mutations of the *KRAS*, *TP53* and *EGFR* genes are commonly expressed across a wide variety of cancers.

The table below sets forth our multiple solid tumor pipeline programs.



Our TCR-T program targeting solid tumors consists of:

- *TCR Library*: We have built a TCR library that targets shared hotspot mutations known to be one of the key causes of cancer. These are non-inherited mutations. We have in-licensed from the National Cancer Institute, or the NCI, multiple TCRs derived from third parties that are reactive to mutated *KRAS*, *TP53* and *EGFR*. Our TCR library currently consists of 12 TCRs targeting six solid tumor indications.
- *Sleeping Beauty Gene Transfer Platform*: Our proprietary non-viral genetic engineering technology utilizes a particular enzyme referred to as a transposase to cut and paste donor DNA referred to as a transposon into chromosomes of a T cell using a process called transposition.
- *hunTR*® (**hu**man **n**eoantigen **T** cell **R**eceptor) *Discovery Engine*: Our robust and innovative TCR discovery engine enables us to rapidly identify new TCRs to add to our ever-expanding TCR library. Using our *hunTR* discovery engine, we are able to analyze thousands of single T cells simultaneously using state-of-the-art bioinformatics and next generation sequencing. We aim to maximize the breadth of our TCR library by evaluating both helper (CD4) and killer (CD8) T cells. The ability to continue discovering new TCRs has the potential to expand the applicable patient population for our ongoing and future clinical trials.

We believe our TCR-T program has several potential advantages over other cell therapy approaches for solid tumors, including CAR-T and tumor-infiltrating lymphocytes, or TIL. As compared to CAR-T, these potential advantages include that our TCR-T program targets intracellular and extracellular neoantigens whereas CAR-T primarily targets extracellular antigens. As compared to TIL, these potential advantages include that our TCR-T program has defined target specificity from the genetic engineering employed in manufacturing whereas in TIL specificity typically arises from the endogenous TCR rather than an introduced immunoreceptor.

Background on TCRs

Our strategy is to target the hallmark of genomic instability in cancer with TCRs. Genes in cancer cells can lead to the production of proteins, which are then processed by the cell into protein fragments known as peptides. These peptides are presented to T cells by a specialized set of molecules on the cancer cell surface called the human leukocyte antigen, or HLA, system. When peptide presentation occurs, and it results in T cell activation through the TCR, the peptides are known as antigens.

When these immunogenic peptides are derived from proteins which are in turn expressed from genes that are mutated only in tumor cells (for example, within the cancer genome and not encoded in the germline), they are known as neoantigens. Tumor cells presenting neoantigens via HLA are targets for T cells. T cells can recognize and kill neoantigen-presenting cancer cells. This approach is different from traditional CARs, which directly recognize antigens, such as CD19, on the surface of malignant B cells, without presentation by HLA.

In general, the immune system avoids targeting the body's own healthy cells principally through processes known as immune tolerance by which T cells do not respond to HLA containing peptides from normal proteins. The recognition by the TCR of a peptide presented by the HLA system is a vital immune mechanism that allows the body both to respond against foreign threats, including cancer, as well as to avoid targeting the body's own healthy cells.

Tumors utilize a variety of strategies to evade and suppress the host immune system. This often renders T cells residing within the tumor, referred to as TILs, ineffective and, despite expressing tumor-specific TCRs, unable to recycle their effector functions to kill tumors. To overcome immune suppression, healthier T cells are likely needed, such as those found in the peripheral blood. However, these circulating T cells do not typically express tumor-specific TCRs in adequate numbers.

Neoantigens are encoded by tumor-specific mutated genes that are often unique to each patient. Targeting these unique neoantigens requires TCRs that are generated on a patient-by-patient basis. During cancer initiation and progression, tumor cells acquire mutations in naturally occurring genes that are responsible for transformation, known as driver mutations. Some of these driver mutations occur in common places called hotspots and are a class of mutations shared between tumor types and between individuals. Since driver mutations can be anticipated, it is possible to prepare TCRs in advance of a patient's need and form a library of banked TCRs.

Our Approach to Targeting Neoantigens

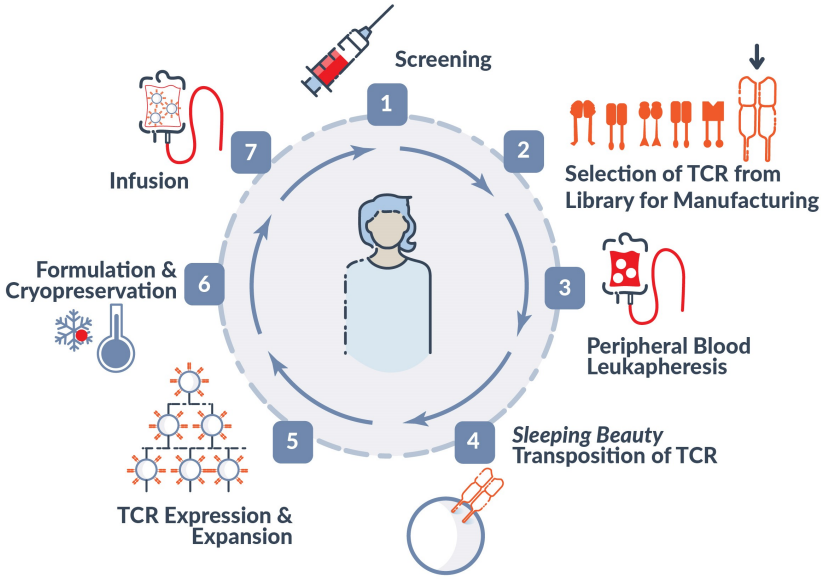
We believe that to be successful in treating solid tumors, genetically modified T cells targeting one or more neoantigens will likely need to address the fact that (1) among a population of patients, not all tumors express the targeted neoantigen, referred to as inter-tumor heterogeneity, and (2) within a single patient, not all tumor cells express the targeted antigen, referred to as intra-tumor heterogeneity. Inter-tumor heterogeneity limits the number of recipients that are eligible to receive a treatment and intra-tumor heterogeneity creates the risk of antigen-escape variants, increasing the likelihood of cancer relapse. As a result, we believe companies developing T cell therapies targeting neoantigens must address both inter- and intra-tumor heterogeneity.

We genetically modify peripheral blood-derived T cells to express TCRs with specificity to tumor-derived antigens, especially neoantigens, and propagate them to sufficient numbers prior to administration. We aim to overcome the key challenges of targeting neoantigens by using DNA plasmids to reprogram T cells to express introduced TCRs on a patient-by-patient basis. This is designed to help address tumor heterogeneity.

Our TCR-T cells contain multiple different subsets of T cells, including effector and memory T cells. The effector T cells are associated with immediate anti-tumor activity. Memory T cells have greater growth potential relative to the effector T cells. Some of our TCR-T cells are T memory stem cells, which have been described to have the largest capacity for growth and renewal relative to other T-cell populations.

Our TCR-T Manufacturing Process

The diagram below illustrates our manufacturing process for our current TCR-T product candidates.



Our TCR-T approach focuses on what we believe to be the most critical and prevalent tumor-specific targets in cancer. These target mutations, called hotspots, are prevalent in genes including *KRAS, TP53* and *EGFR,* which can be found in non-small cell lung, colorectal, endometrial, pancreatic, ovarian and bile duct cancers in several different HLA alleles. These driver genes play a key role in regulating cell division, maturation and death, and mutations in these genes have been observed to play a critical role in the development of certain cancers. The advantage of our Library TCR-T approach is that subsets of patients with solid tumors may be rapidly treated by screening them for targeted neoantigens (e.g., *KRAS*, *TP53* and *EGFR*), identifying patient HLA, and matching these results to the TCRs in the library. Patients with a variety of different cancers (e.g., non-small cell lung, colorectal, endometrial, pancreatic, ovarian and bile duct cancers) can be screened for a match to our growing TCR library through tumor sequencing and identification of the patient's tumor mutation and HLA typing. Once a match to our TCR library is confirmed, a portion of the patient's white blood cells is collected through a peripheral blood leukapheresis and sent to our own current Good Manufacturing Practices, or cGMP, manufacturing facility in Houston, Texas.

Once the desired pre-manufactured TCR transposon is selected from our TCR library, we utilize our proprietary non-viral *Sleeping Beauty* genetic engineering technology to modify the patient's T cells (both CD4+ and CD8+). We use T cells from peripheral blood, which have a younger and healthier phenotype relative to tumor-resident T cells, to generate our TCR-T cells. Given initial clinical cellular kinetics of the TCR-T cells in the patients treated to date, we believe these modified TCR-T cells will persist in the recipient following infusion. We have observed in preclinical studies that genetic engineering of T cells by our *Sleeping Beauty* technology resulted in the rapid and stable expression of the introduced neoantigen-specific TCR. The genetically modified T cells expressing high levels of the TCR are expanded to produce the patient-specific, or autologous, TCR-T cell product. The product candidate is then harvested from the manufacturing process, formulated, cryopreserved, transferred to the hospital facility and infused in the patient after thawing.

Benefits of Our Non-Viral Sleeping Beauty Gene Transfer Platform

Our *Sleeping Beauty* gene transfer platform provides several benefits, including those described below.

- *Scalability and Reduction in Complexity*. The *Sleeping Beauty* technology is a straightforward means to manufacture a large number of autologous T-cell products. The technology requires only the synthesis of DNA plasmids as the starting material for genetic engineering of the T cells. In contrast, traditional viral gene transfer is more complex and requires specialized manufacturing of each viral vector(s) of interest. Production of a viral vector starts with the generation of plasmid DNA with the transgene of interest. This plasmid is then introduced into a packaging cell line and viruses are secreted into the media over a couple of days. This process is inherently more complex to scale with the numbers of cells and associated media required relative to *Sleeping Beauty,* which only requires the plasmid DNA. Genetic modification of the patient cells using the *Sleeping Beauty* technology is accomplished through electroporation with the DNA plasmids and subsequent culture, selection and growth of the T cells to large numbers using traditional manufacturing techniques. This simple process can be scaled through the addition of manufacturing lines.
- *Customizable Therapies*. We believe our *Sleeping Beauty* platform provides us with the ability to manufacture more customizable therapies. The platform enables a library of TCRs to be assembled and used in cells to recognize diverse mutations within shared

neoantigens and address a multitude of HLA types. We believe this can enable both our current Library TCR-T approach against shared cancer targets as well as personalized TCR therapies against unique, and potentially multiple, personal neoantigens. We believe multiplexing TCR-T cells, which involves infusing a patient with more than one TCR product, will be best enabled by our *Sleeping Beauty* system and through our unique TCRs and expanding TCR library.

- *Potential Clinical Benefits*. We believe the anti-tumor activity of our TCR-T cells has the potential to last as long as the TCR-T cells persist and proliferate following the recognition of the neoantigen on the tumor cell surface. This may lead to durable and progressively greater clinical response in patients. In CAR-T cell products generated in human cells, *Sleeping Beauty* transposons were observed to integrate in a close-to-random distribution at thymine-adenine, or TA, dinucleotide sites, which increases the likelihood of insertion in a genomic safe harbor, thereby making them less likely to cause off-target effects when compared to other transposons and viral gene delivery methods. We also believe that including membrane-bound interleukin-15, or mbIL-15, in TCR-T cells can provide additional benefits. In particular, we have observed that T cells modified to express mbIL-15 as well as a TCR show increased potential for stemness corresponding with a potential ability to persist longer in the patient after infusion.
- *Accommodation of Large Transgene Size*. Plasmids manufactured using our *Sleeping Beauty* platform have a large enough payload size to allow for genetic engineering of both the TCR as well as insertion of a gene encoding for the expression of cytokines, such as mbIL-15. This facilitates uniformly high co-expression of both the TCR and cytokine on a single integrated gene.

Preclinical and Clinical Development

Preclinical Development of our TCR-T Product Candidates

We have independently evaluated all licensed TCRs using our *Sleeping Beauty* platform. Candidate TCRs for clinical translation were selected based on conventional *in vitro* immunological measurements. We presented these data at the 2021 American Association for Cancer Research (AACR) and Society for Immunotherapy of Cancer (SITC) annual meetings. We selected the TCRs based, in part, on their ability to express on the T cell surface and then specifically recognize the mutated target without also targeting healthy cells. For those TCRs that are destined for killer T cells, our preclinical data suggest that those TCR-T cells can kill the appropriate tumor cell lines expressing the target neoantigen. In our preclinical studies we observed TCR-T cells killed significantly more tumor cells when matched with the corresponding HLA and neoantigen relative to mismatched tumor cells and relative to mismatched T cells not expressing the relevant neoantigen-specific TCR.

Selected licensed TCRs have also been co-expressed with mbIL-15 on T cells. This was accomplished with the transfer of a single transposon to deliver three independent genes (TCRalpha, TCRbeta, mbIL-15) to the T cell. We optimized the orientation order of these three genes and the growth conditions specific for the generation of mbIL-15 TCR-T cells. Using similar standard immunologic readouts described above, the mbIL-15 TCR-T cells were observed to display a similar specificity and potency profile to conventional TCR-T cells; however, we observed increased *in vitro* survival of mbIL-15 TCR-T cells in the absence of all added support relative to TCR-T cells, especially in the T memory stem cell populations. We have filed an international patent application around these findings and presented preclinical data from this program at the American Society of Gene & Cell Therapy conference in 2022. We believe mbIL-15 has the potential to increase the survival of TCR-T cells in the harsh tumor microenvironment and deepen clinical responses. We are working towards filing a related Investigational New Drug Application, or IND, in the second half of 2023.

TCR-T Library Phase 1/2 Trial

In February 2021, we received FDA clearance for our company-sponsored IND to initiate a Phase 1/2 open-label, dose-escalation trial which is initially being conducted at MD Anderson. In January 2022, after screening patients, we opened enrollment in our TCR-T Library Phase 1/2 Trial and expect to enroll up to 180 adults during the course of the trial. We will only enroll patients who have a matched HLA and hotspot mutation that is targeted by one of the TCRs from our TCR library, who have progressive or recurrent solid tumors and who have failed at least one prior line of standard therapy. The trial is evaluating our 12 library TCRs targeting neoantigens arising from *KRAS*, *TP53* and *EGFR* mutations in patients across a broad range of solid tumors that include non-small cell lung, colorectal, endometrial, pancreatic, ovarian, and bile duct cancers, all in a single trial. We have used and anticipate continuing to use our hunTR discovery engine to add new TCRs to our library and clinical program as they are qualified by our laboratory. The patients are being enrolled in cohorts according to their cancer at three separate dose levels. The Phase 1 primary endpoint is to define dose limiting toxicity or the recommended maximum tolerated dose for a subsequent clinical trial. The primary endpoints for the Phase 2 portion of the trial are expected to determine the objective response rate and otherwise evaluate safety and tolerability. We are also monitoring TCR-T cell persistence and performing multiple conventional immune monitoring assays in the clinical trial to evaluate their persistence in patients. As of December 31, 2022, we have enrolled and dosed three patients.

We presented information on the first two patients treated in September 2022 at the CRI-ENCI-AACR International Cancer Immunotherapy Conference, or CICON. The first patient we treated had lung adenocarcinoma with multiple lines of prior therapy and was refractory to checkpoint inhibitors. The second patient we treated was diagnosed with colon cancer and had received multiple lines of standard prior therapies. We successfully dosed a third patient who was diagnosed with advanced pancreatic cancer refractory to multiple lines of standard therapy in our TCR-T Library Phase 1/2 Trial in December 2022. We continue to perform translational assessments to assess the biological activity of our TCR-T cells in order to guide next generation TCR-T therapy approaches including potential combination and multiplexed

TCR-T cell therapies. We believe that these data provide early clinical validation of the potential of *Sleeping Beauty* TCR-T cell therapy in high value indications with significant unmet need.

- Patients 1, 2 and 3 demonstrated manageable safety profiles with no dose limiting toxicities, or DLTs, or immune effector cell-associated neurotoxicity syndrome;
- Persistence of the TCR-T cells has been observed. Patient 1 had persistence at 24 weeks with approximately 30% of the patient's total CD3+ T cells comprising TCR-T cells in peripheral blood after treatment with KRAS-G12D/HLA-A*11:01 mutation-specific TCR-T cells at dose level 1 ($9x10^9$ cells). Patient 2 had persistence at 12 weeks with approximately 20% of the patient's total CD3+ T cells comprising TCR-T cells in peripheral blood after treatment with TP53-R175H/HLA-A*02:01 mutation-specific TCR-T cells at dose level 2 ($64x10^9$ cells).
- Demonstrating six month progression-free survival, Patient 1 had best overall response of objective, partial response with regression of greater than 50% of target lesions at 12 weeks post-cell therapy. Patient 2 had best overall response of stable disease at six weeks with 12 week progression-free survival. Progressive disease was observed in Patient 1 and Patient 2 at weeks 24 and 12, respectively, and each patient subsequently went off study;
- The targeted mutations, KRAS-G12D and TP53-R175H, were detected in progressing tumor biopsies suggesting no antigen loss; and
- Tumor homing was observed in Patient 1 with infiltration of both CD4 and CD8 TCR-T cells six months post-TCR-T cell therapy.

To our knowledge, achievement of an objective clinical response resulting from treatment with KRAS-G12D and HLA-A*11:01 specific TCR-T cells has not been reported until Patient 1 in our TCR-T Library Phase 1/2 Trial. Patient 1's infusion product was high quality with 97.3% viability, 99.7% CD3+ purity and 95.2% TCR positivity. Patient 1's target lesions were reduced compared to baseline by 46% at six weeks, 51% at 12 weeks and 46% at 24 weeks. At six months following treatment, an elective tumor biopsy of non-measurable disease in the right lung showed continued presence of tumor cells, KRAS-G12D mutation and HLA-A*11:01 allele, and progressive disease was corroborated by another elective scan at seven months. Patient 1 is now off trial and is being monitored as part of our long-term follow-up protocol.

Patient 2's treatment was the first-in-human *Sleeping Beauty* TCR-T cell therapy targeting TP53 hotspot mutations and was generally well tolerated. The same TCR used by the NCI to treat breast cancer, which resulted in a 6-month confirmed, objective partial response, was used to treat Patient 2. Patient 2 received highly pure TCR-T cells (92.5% viability, 99% CD3+ purity, and 92% TCR positivity). Reduction of target lesions by 15% from baseline was observed at six weeks post-infusion, but we observed 21.8% growth of lesions from the week six measurements and appearance of new liver and lung metastases at week 12 signaled progressive disease in Patient 2, who was removed from the trial as a result of such progression.

In the fourth quarter of 2022, we submitted an IND amendment to the FDA to add two new TCRs to our clinical trial targeting frequent mutations and HLAs, with the potential to double the addressable market of our TCR-T Library Phase 1/2 Trial. In over 700 patients screened at MD Anderson Cancer Center with gastrointestinal or lung tumors, we have improved our match rate from 5% ot over 10%, including roughly one in five patients matching two TCRs in the current library. The addition of these new TCRs highlights our strategy to add both more HLAs to existing mutations (KRAS-G12V and HLA-DRB1*07:01) and new mutations within our targeted gene families (TP53-R273C and HLA-DPB1*04:02). In 2023, we expect to further expand our library with exclusively owned TCRs targeting recurrent hotspot mutations in *KRAS, TP53* and *EGFR* to 15 TCRs. We continue to actively enroll patients in our TCR-T Library Phase 1/2 Trial targeting *KRAS, TP53* and *EGFR* hotspot mutations across six solid tumor indications. We expect to enroll multiple patients in the first half of 2023. The IND amendment also combined our treatment and screening protocols, streamlining enrollment and potentially making it easier for both patients and physicians. The amended IND also eliminated the requirement for retesting of the tumor mutation if six months had passed between screening and treatment. We anticipate providing an interim clinical data update in 2023 as we work toward advancing the TCR-T Library Phase 1/2 Trial into Phase 2 and we expect to be Phase 2 ready by the end of 2023.

IL-12 Program

As we announced in May 2021, we are winding down our existing Controlled IL-12 clinical program for the treatment of recurrent glioblastoma multiforme. We are actively seeking a partner for continued development of this program.

Manufacturing

Our cGMP facility in Houston, Texas is staffed by Alaunos personnel and is fully operational for manufacturing TCR T-cells genetically modified with our *Sleeping Beauty* gene transfer platform for our early-stage clinical trials. We continue to rely on third parties for the production of the DNA plasmids used in manufacturing our product candidates.

Our Library TCR-T approach allows us to streamline the T cell manufacturing process by pre-manufacturing DNA plasmids corresponding to each of our qualified library TCRs. These TCRs are then utilized in the manufacturing for the patient-specific, autologous TCR-T product candidates. Our in-house TCR-T manufacturing facility also allows us to integrate our research and development capabilities, potentially reducing the time from discovery to treating patients in a clinical trial. This integration is designed to minimize delays and reduce risks that can

be encountered in drug development, including the failure of third parties to successfully produce the desired product, long technology transfer periods and long lead times for orders. We continue to execute on our multi-pronged strategy to expand manufacturing capacity and efficiency. We doubled our manufacturing capacity in 2022, allowing for production of two products simultaneously. We also filed an IND amendment to move from fresh to cryopreserved product and began implementing this change in the first half of 2023. The use of cryopreserved cell products is expected to reduce manufacturing process time from 30 days to 26 days, a 13% decrease, while increasing flexibility for patient scheduling and treatment. We have ongoing initiatives to optimize the process and further reduce the manufacturing time.

We seek continuous improvement in our manufacturing and release workflow through process and analytical development. Our processes will continue to be optimized to increase efficiencies, incorporate new technologies and reduce time to treatment for the patient.

Intellectual Property

Our goal is to obtain, maintain and enforce patent and trade secret protection for our product candidates, formulations, processes, methods and other proprietary technologies. We strive to preserve our trade secrets and other confidential information and to operate without infringing the proprietary rights of other parties. Our policy is to actively seek the strongest possible intellectual property protection for our technology and product candidates through a combination of license agreements and owned patents, both in the United States and abroad.

Owned Patents

As of December 31, 2022, we have five families of pending patent applications that cover our TCR-T library, products and processes. We do not currently own any granted patents.

Patent terms extend for varying periods according to the date of patent filing or grant and the legal patent terms in the various countries where patent protection is obtained. The actual protection offering by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage, the issued claims and the availability of legal remedies in the country.

Pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, some of our patents, under certain conditions, may be eligible for limited patent term extension for a period of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. However, this extension period cannot be extended beyond 14 years from the drug's approval date. The patent term restoration period is generally one-half the period of time elapsed between the effective date of an IND application or the issue date of the patent, whichever is later. The submission date of a New Drug Application, or NDA, plus the period of time between the submission date of the NDA or the issue date of the patent, whichever is later, and FDA approval. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves applications for any patent term extension or restoration. We intend to seek the benefits of this statute, but there can be no assurance that we will be able to obtain any such benefits.

We also depend upon the skills, knowledge and experience of our scientific and technical employees, as well as those of our advisors, consultants, and other contractors, none of which may be patentable. To help protect unpatentable proprietary know-how, and for inventions for which patents may be difficult to enforce, we currently rely, and in the future, will continue to rely, on trade secret protection and confidentiality agreements to protect our interests. To this end, we generally require employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Our patent position and proprietary rights are subject to certain risks and uncertainties. Please read the *"*Risk Related to Our Intellectual Property*"* section for further information about certain risks and uncertainties that may affect our patent position and proprietary rights.

License Agreements

Exclusive License Agreement with PGEN Therapeutics

On October 5, 2018, we entered into an exclusive license agreement, or License Agreement, with PGEN Therapeutics, or PGEN, a wholly owned subsidiary of Precigen Inc., or Precigen, which was formerly known as Intrexon Corporation. Pursuant to the terms of the License Agreement, we have exclusive, worldwide rights to research, develop and commercialize (i) TCR products designed for neoantigens for the treatment of cancer, (ii) products utilizing Precigen's RheoSwitch® gene switch, or RTS, for the treatment of cancer, referred to as IL-12 Products and (iii) CAR products directed to (A) CD19 for the treatment of cancer, referred to as CD19 Products, and (B) BCMA for the treatment of cancer, subject to certain obligations to pursue such target under the License and Collaboration Agreement effective March 27, 2015 between us, Precigen and ARES TRADING S.A., a subsidiary of Merck KGaA, as assigned by Precigen to PGEN. Under the License Agreement, we also have exclusive, worldwide rights for certain patents relating to the *Sleeping Beauty* technology to research, develop and commercialize TCR products for both neoantigens and shared antigens for the treatment of cancer, referred to as TCR Products.

We are solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. We are required to use commercially reasonable efforts, as defined in the License Agreement, to develop and commercialize IL-12 products, CD19 products and TCR Products.

In consideration of the licenses and other rights granted by PGEN, we pay PGEN an annual license fee of $0.1 million and reimbursed PGEN for certain historical costs of the licensed programs.

We will make milestone payments totaling up to an additional $52.5 million for each exclusively licensed program upon the initiation of later stage clinical trials and upon the approval of exclusively licensed products in various jurisdictions. In addition, we will pay PGEN tiered royalties ranging from low-single digit to high-single digit on the net sales derived from the sales of any approved IL-12 products and CAR products. We will also pay PGEN royalties ranging from low-single digit to mid-single digit on the net sales derived from the sales of any approved TCR products, up to a maximum royalty amount of $100.0 million in the aggregate. We will also pay PGEN 20% of any sublicensing income received by us relating to the licensed products. We are responsible for all development costs associated with each of the licensed products.

PGEN will pay us royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of PGEN's CAR products, up to a maximum royalty amount of $100.0 million.

In October 2020, we entered into an amendment to the License Agreement relating to the transfer of certain materials and PGEN's obligations to provide transition assistance relating to the IL-12 products.

License Agreement and 2015 Research and Development Agreement-The University of Texas MD Anderson Cancer Center

On January 13, 2015, we, together with Precigen, entered into that certain license agreement, or the MD Anderson License, with MD Anderson (which Precigen subsequently assigned to PGEN). Pursuant to the MD Anderson License, we, together with PGEN, hold an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson including technologies relating to novel CAR T-cell therapies, non-viral gene transfer systems, genetic modification and/or propagation of immune cells and other cellular therapy approaches, Natural Killer, or NK Cells, and TCRs, arising from the laboratory of Laurence Cooper, M.D., Ph.D. Dr. Cooper served as our Chief Executive Officer from May 2015 until February 2021 and was formerly a tenured professor of pediatrics at MD Anderson.

On August 17, 2015, the Company, Precigen and MD Anderson entered into the Research and Development Agreement, or the 2015 R&D Agreement, to formalize the scope and process for the transfer by MD Anderson, pursuant to the terms of the MD Anderson License, of certain existing research programs and related technology rights, as well as the terms and conditions for future collaborative research and development of new and ongoing research programs. The rights and obligations of Precigen under the 2015 R&D Agreement were assigned to us pursuant to the Fourth Amendment to the 2015 R&D Agreement which was entered into on September 19, 2019, or the Fourth Amendment, with an effective date of October 5, 2018. The activities under the 2015 R&D Agreement are directed by a joint steering committee comprised of two members from our company and one member from MD Anderson.

As provided under the MD Anderson License, we provided funding for research and development activities in support of the research programs under the 2015 R&D Agreement for a period of three years and in an amount of no less than $15.0 million and no greater than $20.0 million per year. On November 14, 2017, we entered into an amendment to the 2015 R&D Agreement extending its term until April 15, 2021 and on October 22, 2019, we entered into another amendment to the 2015 R&D Agreement extending its term until December 31, 2026 and to allow cash resources on hand at MD Anderson under the 2015 R&D Agreement to be used for development costs under the 2019 Research and Development Agreement, or the 2019 R&D Agreement, which we entered into on October 22, 2019, with MD Anderson, pursuant to which we agreed to collaborate with respect to the TCR program.

The term of the MD Anderson License expires on the last to occur of (a) the expiration of all patents licensed thereunder, or (b) the twentieth anniversary of the date of the MD Anderson License; provided, however, that following the expiration of the term of the MD Anderson License, we, together with Precigen, shall then have a fully-paid up, royalty free, perpetual, irrevocable and sublicensable license to use the licensed intellectual property thereunder. After ten years from the date of the MD Anderson License and subject to a 90-day cure period, MD Anderson will have the right to convert the MD Anderson License into a non-exclusive license if we and Precigen are not using commercially reasonable efforts to commercialize the licensed intellectual property on a case-by-case basis. After five years from the date of the MD Anderson License and subject to a 180-day cure period, MD Anderson will have the right to terminate the MD Anderson License with respect to specific technology(ies) funded by the government or subject to a third-party contract if we and Precigen are not meeting the diligence requirements in such funding agreement or contract, as applicable. MD Anderson may also terminate the agreement with written notice upon material breach by us and Precigen, if such breach has not been cured within 60 days of receiving such notice. In addition, the MD Anderson License will terminate upon the occurrence of certain insolvency events for both us and Precigen and may be terminated by the mutual written agreement of us, Precigen, and MD Anderson.

2019 Research and Development Agreement-The University of Texas MD Anderson Cancer Center

Under the 2019 R&D Agreement, we and MD Anderson will, among other things, collaborate on programs to expand our TCR library and conduct clinical trials. The activities under the 2019 R&D Agreement are directed by a joint steering committee comprised of two members from our company and one member from MD Anderson.

We will own all inventions and intellectual property developed under the 2019 R&D Agreement and we will retain all rights to all intellectual property, patentable or not, for oncology products manufactured using non-viral gene transfer technologies under the 2019 R&D Agreement,

including our *Sleeping Beauty* technology. We have granted MD Anderson an exclusive license for such intellectual property to develop and commercialize autologous TCR products manufactured using viral gene transfer technologies, and any products outside the field of oncology and a non-exclusive license for allogenic TCR products manufactured using viral-based technologies.

Under the 2019 R&D Agreement, we agreed, beginning on January 1, 2021, to reimburse MD Anderson up to a total of $20 million for development costs under the 2019 R&D Agreement, after the funds from the 2015 R&D Agreement are exhausted. In addition, we will pay MD Anderson royalties on net sales of its TCR products at rates in the low single digits. We are required to make performance-based payments upon the successful completion of clinical and regulatory benchmarks relating to its TCR products. The aggregate potential benchmark payments are $36.5 million, of which only $3.0 million will be due prior to the first marketing approval of our TCR products. The royalty rates and benchmark payments owed to MD Anderson may be reduced upon the occurrence of certain events. We also agreed to sell our TCR products to MD Anderson at preferential prices and will sell our TCR products in Texas exclusively to MD Anderson for a limited period of time following the first commercial sale of our TCR products.

The 2019 R&D Agreement will terminate on December 31, 2026 and either party may terminate the 2019 R&D Agreement following written notice of a material breach. The 2019 R&D Agreement also contains customary provisions related to indemnification obligations, confidentiality and other matters.

In connection with the execution of the 2019 R&D Agreement, on October 22, 2019, we issued MD Anderson a warrant to purchase 3,333,333 shares of our common stock, which is referred to as the MD Anderson Warrant. The MD Anderson Warrant has an initial exercise price of $0.001 per share, expires on December 31, 2026 and vests in four parts upon the occurrence of certain clinical milestones. As of December 31, 2022, the milestones have not been met.

The MD Anderson Warrant and the shares of our common stock to be issued upon exercise of the MD Anderson Warrant have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

License Agreement with the NCI

On May 28, 2019, we entered into a patent license agreement, or the Patent License, with the NCI. Pursuant to the Patent License, we hold an exclusive, worldwide license to certain intellectual property to develop and commercialize patient-derived (autologous), peripheral blood T-cell therapy products engineered by transposon-mediated gene transfer to express TCRs reactive to mutated *KRAS*, *TP53* and *EGFR* neoantigens. In addition, pursuant to the Patent License, we hold an exclusive, worldwide license to certain intellectual property for manufacturing technologies to develop and commercialize autologous, peripheral blood T-cell therapy products engineered by non-viral gene transfer to express TCRs, as well as a non-exclusive, worldwide license to certain additional manufacturing technologies. On May 29, 2019, January 8, 2020, September 28, 2020, April 16, 2021, May 4, 2021, and August 13, 2021 we amended the Patent License to expand our TCR library to include additional TCRs reactive to mutated *KRAS* and *TP53* neoantigens licensed from the NCI.

The terms of the Patent License require us to pay the NCI minimum annual royalties in the amount of $0.3 million, which amount will be reduced to $0.1 million once the aggregate minimum annual royalties paid by us equals $1.5 million.

We are also required to make performance-based payments upon successful completion of clinical and regulatory benchmarks relating to the licensed products. Of such payments, the aggregate potential benchmark payments are $4.3 million, of which aggregate payments of $3.0 million are due only after marketing approval in the United States or in Europe, Japan, Australia, China or India. The first benchmark payment of $0.1 million was paid in 2022 upon the initiation of our TCR-T Library Phase 1/2 Trial, which was a qualifying Phase 1 clinical trial under the terms of the Patent License.

In addition, we are required to pay the NCI one-time benchmark payments following aggregate net sales of licensed products at certain aggregate net sales ranging from $250.0 million to $1.0 billion. The aggregate potential amount of these benchmark payments is $12.0 million. We must also pay the NCI royalties on net sales of products covered by the Patent License at rates in the low to mid-single digits depending upon the technology included in a licensed product. To the extent we enter into a sublicensing agreement relating to a licensed product, we are required to pay the NCI a percentage of all consideration received from a sublicensee, which percentage will decrease based on the stage of development of the licensed product at the time of the sublicense.

The Patent License will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. The NCI may terminate or modify the Patent License in the event of a material breach, including if we do not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. We may terminate the Patent License, or any portion thereof, in our sole discretion at any time upon 60 days' written notice to the NCI. In addition, the NCI has the right to: (i) require us to sublicense the rights to the product candidates covered by the Patent License upon certain conditions, including if we are not reasonably satisfying required health and safety needs and (ii) terminate or modify the Patent License, including if we are not satisfying requirements for public use as specified by federal regulations.

Cooperative Research and Development Agreement with the NCI

On January 9, 2017, we entered into a Cooperative Research and Development Agreement, or CRADA, with the NCI. The purpose of this collaboration was to advance a personalized TCR-T approach for the treatment of solid tumors. Using our *Sleeping Beauty* technology, the NCI would analyze a patient's own cancer cells, identify their unique neoantigens and TCRs reactive against those neoantigens and then use our *Sleeping Beauty* technology to transpose one or more TCRs into T cells for re-infusion. Research conducted under the CRADA will be at the direction of Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI, in collaboration with our researchers.

We are responsible for providing the NCI with the test materials necessary for them to conduct their studies, and eventually, clinical trials pursuant to the CRADA. Inventions, data and materials discovered or produced in connection with performance of the research plan under the CRADA will remain the sole property of the party who produced the discovery. The parties will jointly own all inventions jointly discovered under the research plan. The owner of any invention under the CRADA will make the decision to file a patent covering the invention, or in the case of a jointly owned invention, we will have the first opportunity to file a patent covering the invention. If we fail to provide timely notice of our decision to the NCI or decide not to file a patent covering the joint invention, NCI has the right to make the filing. For any invention solely owned by NCI or jointly made by NCI and us for which a patent application was filed, the U.S. Public Health service grants us an exclusive option to elect an exclusive or non-exclusive commercialization license. For inventions owned solely by NCI or jointly owned by NCI and us, which are licensed according to the terms described above, we agreed to grant to the U.S. government a non-exclusive, non-transferable, irrevocable and paid up license to practice the invention or have the invention practiced on its behalf throughout the world. We are also required to grant the U.S. government a non-exclusive, non-transferable, irrevocable and paid up license to practice the invention or have the invention practiced on its behalf throughout the world for any of our solely owned inventions. The agreement may be terminated by any of the parties upon 60 days prior written consent.

The NCI has a cleared IND that would permit them to begin this trial. To our knowledge, the trial has not yet enrolled. The progress and timeline for this trial, including the timeline for dosing patients, are under control of the NCI.

In February 2019, we extended the CRADA with the NCI until January 9, 2022, committing an additional $5.0 million to this program. In March 2022, we entered into an amendment to the CRADA that is retroactive, effective January 9, 2022 to extend the term of the CRADA until January 9, 2023. In June 2022, we entered into the Fourth Amendment to the CRADA, or the CRADA Fourth Amendment, which, among other things, extended the term of the CRADA until January 9, 2025. In connection with the CRADA Fourth Amendment, we agreed to contribute $1.0 million per year, payable on a quarterly basis, beginning in the first quarter of 2023.

TCR-T Platform Licenses

In January 2015, we in-licensed from MD Anderson a technology portfolio that includes intellectual property directed to certain non-viral *Sleeping Beauty* technologies as well as TCR-T cell therapy and bioprocessing technology. Under the terms of the agreement, we have an exclusive license to certain of the intellectual property technology, a co-exclusive license to certain of the intellectual property technology and a non-exclusive license to certain of the intellectual property technology. Our rights to the MD Anderson intellectual property flow to us via our agreement with PGEN.

In May 2019, we in-licensed from the NCI a patent portfolio that includes intellectual property related to our TCR-T cell library. Under the terms of the agreement, we hold an exclusive, worldwide license to certain intellectual property to develop, manufacture and commercialize patient-derived (autologous), peripheral blood T-cell therapy products engineered by transposon-mediated gene transfer to express TCRs reactive to mutated *KRAS*, *TP53* and *EGFR* neoantigens. In addition, we hold an exclusive, worldwide license to certain intellectual property for manufacturing technologies to develop and commercialize autologous, peripheral blood T-cell therapy products engineered by non-viral gene transfer to express certain TCRs, as well as a non-exclusive, worldwide license to certain additional manufacturing technologies.

Governmental Regulation and Product Approval

As a biopharmaceutical company, we are subject to extensive regulation. Our genetically engineered T-cell product candidates are regulated as biologics. With this classification, commercial production of our products will need to occur in registered and licensed facilities in compliance with cGMPs for biologics.

Human immunotherapy products are a new category of therapeutics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization.

Government authorities in the United States (at the federal, state and local level) and in other countries and jurisdictions extensively regulate, among other things, the research, development, preclinical and clinical testing, manufacturing, quality control, labeling, packaging, storage, record-keeping, promotion, advertising, sale, 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 agency 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. The process for obtaining regulatory marketing approvals and the subsequent compliance with applicable 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 under the Public Health Service Act, or PHSA, and the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters and similar public notice of alleged non-compliance with laws, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be approved for marketing in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies according to Good Laboratory Practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as Good Clinical Practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- preparation and submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP to assure that the facilities, methods and controls used in product manufacture are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current Good Tissue Practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA;
- payment of user fees for FDA review of the BLA; and
- FDA acceptance, review and approval, or licensure, of the BLA, which might include review by an advisory committee, a panel typically consisting of independent clinicians and other experts who provide recommendations as to whether the application should be approved and under what conditions.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate must undergo rigorous preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations as well as *in vitro* and animal studies to assess the potential safety and efficacy of the product candidate. The clinical trial sponsor must submit an IND to the FDA before clinical testing can begin in the United States. An IND must contain the results of the preclinical tests, manufacturing information, analytical data, any available clinical data or literature, a proposed clinical protocol, an investigator's brochure, a sample informed consent form and other materials. Clinical trial protocols detail, 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. Some preclinical testing, such as toxicity studies, may continue even after the IND is submitted.

The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials or 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.

Further, each clinical trial must be reviewed and approved by an independent institutional review board, or 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. Clinical trials involving recombinant or synthetic nucleic acid molecules also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical

research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements.

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 and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the target disease or condition.
- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population, generally at geographically dispersed clinical trial sites. These clinical trials are intended to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk to benefit profile of the product and to provide an adequate basis for product labeling.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all.

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 agencies 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, the NIH and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate 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. The FDA or the sponsor or its data safety monitoring board, an independent group of experts that evaluates study data for safety and makes recommendations concerning continuation, modification, or termination of clinical trials, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional nonclinical 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.

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug or biologic products that meet certain criteria. Specifically, new drugs or biologics 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. Unique to a fast track product, 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.

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, 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 approved 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 begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA 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. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the biological product, which 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. FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues and cellular and tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA GTP regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. 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.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval. If the agency decides not to approve the BLA in its present form, the FDA will issue a Complete Response Letter, which generally outlines the specific deficiencies in the BLA identified by the FDA and may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Even with the submission of additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria 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.

The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, 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. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

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.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements and complying with FDA promotion and advertising requirements.

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. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. 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 cGMP 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.

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

Moreover, the FDA strictly regulates marketing, labeling, advertising and promotion of products. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. However, companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA and other agencies 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 liability.

U.S. Marketing Exclusivity

The Biologics Price Competition and Innovation Act, or BPCIA, amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. Biosimilars are approved pursuant to an abbreviated pathway whereby applicants need not submit the full slate of preclinical and clinical data, and approval is based in part on the FDA's findings of safety, purity, and potency for the original biologic (i.e., the reference product). Reference products are eligible to receive 12 years of exclusivity from the time of first licensure of the product, which prevents the FDA from approving any biosimilars to the reference product through the abbreviated pathway, but does not prevent approval of BLAs that are accompanied by a full data package and that do not rely on the reference product. A biosimilar may be approved if the product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences with the reference product in terms of the safety, purity and potency.

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.

Orphan Drug Designation

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

If a product that has orphan 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 to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Orphan drug status in the European Union, or EU, has similar but not identical benefits in that jurisdiction.

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 significant 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, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. Third-party payors are increasingly challenging the price, examining the medical necessity of and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

Reimbursement may impact the demand for, and/or the price of, any product candidate that obtains marketing approval. Even if coverage and reimbursement is obtained for a given product candidate by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use a product, and physicians may be less likely to prescribe a product, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of the product. Therefore, coverage and adequate reimbursement is critical to new drug product acceptance.

The downward pressure on health care costs in general, particularly prescription drugs and biologics, has become very intense. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. As a result, increasingly high barriers are being erected to the entry of new products. 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 favorable coverage and adequate reimbursement. In addition, emphasis on managed care in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. 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.

Health Care Laws Governing Interactions with Healthcare Providers

Healthcare providers and third-party payors in the United States play a primary role in the recommendation and prescription of drug products. Arrangements with healthcare providers, third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws, including false claims, privacy and security, price reporting and physician sunshine laws or regulations. Some of our pre-commercial activities are subject to some of these laws. The applicable federal, state and foreign healthcare laws and regulations laws that may affect a pharmaceutical manufacture's ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which regulates our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- Federal civil and criminal false claims laws, including the False Claims Act which permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal civil and criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities and individuals subject to the law including certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as individuals and entities that perform services for them which involve the use, or disclosure of, individually identifiable health information, known as business associates as well as their covered subcontractors;
- Requirements to report annually to the Centers for Medicare & Medicaid Services, or CMS, certain financial arrangements with physicians and teaching hospitals, as defined in the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, and its implementing regulations, including reporting any "transfer of value" made or

distributed to prescribers and teaching hospitals, and reporting any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year; and

- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities; state laws that require the reporting of information related to drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that a pharmaceutical manufacturer's business practices do 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 a pharmaceutical manufacturer, and it is not successful in defending itself or asserting its rights, it may be subject to the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, as well as additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. In addition, the approval and commercialization of drug products outside the United States may also subject a pharmaceutical manufacturer to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Healthcare Reform Efforts

A primary trend in the United States healthcare industry and elsewhere is cost containment. Over the last several years, there have been federal and state proposals and legislation enacted regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products and making changes to healthcare financing and the delivery of care in the United States.

In March 2010, President Obama signed into law the ACA, which included measures that have significantly changed the way healthcare is financed by both governmental and private insurers. The ACA, among other things, imposed 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, extended the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or reformulated drugs, established annual fees on manufacturers and importers of certain branded prescription drugs and biologic agents, promoted a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program and imposed a number of substantial new compliance provisions related to pharmaceutical companies' interactions with healthcare practitioners. The ACA also expanded eligibility for Medicaid programs and introduced a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research and a new Center for Medicare & Medicaid Innovation at CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, legal and political challenges to certain aspects of the ACA. For example, President Trump signed several executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Further, President Biden issued an executive order that instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act, 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 implementing a newly established

manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact ACA and our business. The ultimate content, timing or effect of any healthcare reform measures on the U.S. healthcare industry is unclear.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which went into effect on April 1, 2013. This 2% reduction was temporarily suspended during the COVID-19 pandemic, but has since been reinstated and, unless Congress and/or the Executive Branch take additional action, will begin to increase gradually starting in April 2030, reaching 4% in April 2031, until sequestration ends in October 2031. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. In November 2019, CMS issued a final rule finalizing the changes to the Medicare Quality Payment Program.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 30, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers; the implementation of these provisions has also been delayed by the IRA until January 1, 2032. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden Administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry.

At the state level, legislatures have increasingly enacted 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

U.S. Foreign Corrupt Practices Act, U.K. Bribery Act and Other Laws

The Foreign Corrupt Practices Act, or the FCPA, prohibits any United States 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. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

Our operations are also subject to non-United States anti-corruption laws such as the U.K. Bribery Act 2010, or the Bribery Act. As with the FCPA, these laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or

gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States and authorities in the EU, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as trade control laws.

Failure to comply with the Bribery Act, the FCPA and other anti-corruption laws and trade control laws could subject us to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses.

Competition

We believe our novel hunTR discovery engine has a demonstrated ability to identify proprietary TCRs, allowing us to further expand and advance our pipeline with multiple solid tumor programs under development. In addition, our non-viral transposon method of expressing TCRs, *Sleeping Beauty,* is less complex relative to many of our competitors' viral approaches. Finally, our TCR-T Phase 1/2 Library Trial is designed to allow us to treat patients quickly and efficiently in many different indications with a tumor mutation and HLA matching one or more of the several TCRs in our library, which we believe gives us a distinct competitive advantage. However, the development and commercialization for new products to treat cancer, including the indications we are pursuing, is highly competitive and considerable competition exists from major pharmaceutical, biotechnology and specialty cancer companies. Many of these companies have more experience in preclinical and clinical development, manufacturing, regulatory, and global commercialization. Given the rapidly advancing and changing science and technologies in the industry, they may compete with us in hiring personnel, setting up clinical study sites, recruiting patients for clinical trials, and procuring technologies and licenses complementary to, or required for, our programs. We are also competing with academic institutions, governmental agencies and private organizations that are conducting research in the field of cancer.

Our TCR-T cell therapies targeting solid tumors face significant competition from multiple companies, and their collaborators, in the TCR and CAR technology space. We face competition from several companies, including 2Seventy Bio, Achilles Therapeutics, Adaptimmune Therapeutics, Affini-T Therapeutics, Annoca, ArsenalBio, Athenex, BioNTech, Bristol-Myers Squibb, Immatics, Iovance Biotherapeutics, Kite (a Gilead company), Lion TCR, Lyell Immunopharma, Medigene, Nurix Therapeutics, Neogene Therapeutics (a member of the AstraZeneca group), NexImmune, PACT Pharma, Precigen, Tactiva Therapeutics, Takara Bio, TCR^2 Therapeutics, T-Cure BioScience, T-knife Therapeutics, Triumvira Immunologics, TScan Therapeutics, Turnstone Biologics, Zelluna Immunotherapy and others. Many of these companies are either investigating TCR-T cells against germline antigens or are utilizing tumor infiltrating lymphocytes. Some are pursuing CAR-T cells for solid tumors. In contrast, we are focused on developing TCR-T cell products against neoantigens arising from somatic mutations in solid tumors.

Companies in the T-cell therapy segment that have target discovery platforms like ours include Adaptive Biotechnologies, Affini-T Therapeutics, Enara Bio, Immatics, Neogene Therapeutics (a member of the AstraZeneca group), PACT Pharma, T-knife Therapeutics, TScan Therapeutics and 3T Biosciences. Several companies, including Advaxis, Amgen, BioNTech, Geneos Therapeutics, and Gritstone, are pursuing vaccine platforms to target neoantigens for solid tumors. Other companies are developing non-viral gene therapies, including Poseida Therapeutics and several companies developing CRISPR technology, including Captain T Cell and Crispr Therapeutics.

Several companies are pursuing the development of allogeneic CAR-T therapies, including Allogene Therapeutics, Atara Biotherapeutics and Precision Biosciences, which may compete with our product candidates. We also face competition from companies developing therapies using cells other than T cells, such as Athenex, Fate Therapeutics, ImmunityBio, IN8bio, Nkarta Therapeutics and Takeda Pharmaceutical. Other competitors are developing T cells with cytokines, such as Fate Therapeutics and Obsidian Therapeutics. Finally, we also face competition from non-cellular treatments offered by other companies, such as Amgen, AstraZeneca, Bristol-Myers Squibb, Immatics, Immunocore, Incyte, Merck, Mirati and Roche. Additionally, our ability to find partnerships relating to our IL-12 and CAR-T programs may be impacted by substantial competition from these and other biopharmaceutical companies.

We face competition on a broader spectrum of the oncology market that is more common, cost-effective and reimbursable, such as surgery, radiation and other drug therapies like chemotherapy, hormone therapy, biologic therapy such as monoclonal and bispecific antibodies, or a combination of any of these therapies. If any of our TCR-T therapies are approved, they may not be as competitive as other therapies, to the extent they are used in combinations with these therapies. Insurers and other third-party payors may also encourage use of certain products; thus, gaining market acceptance or market share for any of our TCR-T therapies could pose difficulties. Finally, standard of care could evolve or change throughout the clinical development of our product candidates.

Moreover, if our competitors develop and market a drug that is safer, more effective with fewer side effects, easier to administer, or less expensive, we could see a less favorable market opportunity for our TCR-T therapy candidates. Our competition may also receive FDA or other regulatory approval for their products more quickly than we do, which could give them a first mover advantage and a strong market position before we are able to commercialize our products. If approved, key competitive factors that may affect the success of our TCR-T candidates are likely their efficacy, safety, ease of administering, price and reimbursement from insurance or government.

Employees and Human Capital Resources

As of February 15, 2023, we had 34 full-time employees and no part-time employees, 28 of whom were engaged in research and development activities, and 6 of whom were engaged in administration. None of our employees are subject to a collective bargaining agreement and we believe our relations with our employees are good.

Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees.

We recruit the best people for the position regardless of gender, ethnicity or other protected traits and it is our policy to fully comply with all laws applicable to discrimination in the workplace. Our diversity, equity and inclusion principles are also reflected in our employee training and policies.

The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Corporate Information

We originally incorporated in Colorado in September 1998 (under the name Net Escapes, Inc.) and later changed our name to "EasyWeb, Inc." in February 1999. We re-incorporated in Delaware on May 16, 2005 under the same name. On September 13, 2005, we completed a "reverse" acquisition of privately held Ziopharm, Inc., a Delaware corporation. To effect this transaction, we caused ZIO Acquisition Corp., our wholly-owned subsidiary, to merge with and into Ziopharm, Inc., with Ziopharm, Inc. surviving as our wholly owned subsidiary. Following the merger, we caused Ziopharm, Inc. to merge with and into us and we changed our name to "Ziopharm Oncology, Inc." As a result, Ziopharm, Inc. became the registrant with the Securities and Exchange Commission, or the SEC, and the historical financial statements of Ziopharm, Inc. became our historical financial statements. On January 25, 2022, we filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation with the Delaware Secretary of State to change our name to Alaunos Therapeutics, Inc.

Our principal executive offices are located at 8030 El Rio Street, Houston, Texas 77054, and our telephone number is (346) 355-4099.

Available Information

Our website address is www.alaunos.com. Our website and information included in or linked to our website are not part of this Annual Report on Form 10-K. We file reports with the SEC, which we make available on our website free of charge. These reports include annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to such reports, each of which is provided on our website as soon as reasonably practicable after we electronically file such materials with or furnish them to the SEC. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers, like us, that file electronically with the SEC.

Item 1A. Risk Factors

An investment in our common stock is risky. In addition to the other information in this Annual Report on Form 10-K, you should carefully consider the following risk factors in evaluating us and our business. If any of the events described in the following risk factors were to occur, our business, financial condition, results of operation and future growth prospects would likely be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose all or a part of your investment in our common stock. Therefore, we urge you to carefully review this entire report and consider the risk factors discussed below. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, financial condition, operating results or prospects. Additional risks that we currently do not know about, or that we currently believe to be immaterial, may also impair our business. Certain statements below are forward-looking statements. See "Special Note Regarding Forward-Looking Statements" in this Annual Report.

RISKS RELATED TO OUR BUSINESS

We will require substantial additional financial resources to continue as a going concern and to continue ongoing development of our product candidates and pursue our business objectives; if we are unable to obtain these additional resources when needed, we may be forced to delay or discontinue our planned operations, including clinical testing of our product candidates.

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the year ended December 31, 2022, we had a net loss of $37.7 million, and, as of December 31, 2022, our accumulated deficit since inception in 2003 was $880.6 million. We expect our operating expenditures and net losses to increase significantly in connection with our ongoing clinical trial and our internal research and development capabilities. Further development of our product candidates will require substantial increases in our expenses as we:

- continue to undertake clinical trials for product candidates;
- scale-up and scale-out the manufacturing of our TCR-T product candidates;
- seek regulatory approvals for product candidates;
- work with regulatory authorities to identify and address program-related inquiries;
- implement additional internal systems and infrastructure; and
- hire additional personnel, including highly-skilled and experienced scientific staff.

As of December 31, 2022, we have approximately $53.0 million of cash and cash equivalents, including $13.9 million of restricted cash related to the Amended Loan and Security Agreement (as defined below). Given our current development plans and cash management efforts, we anticipate cash resources will be sufficient to fund operations into the fourth quarter of 2023. We have no committed sources of additional capital at this time. We follow the guidance of Accounting Standards Codification, or ASC, Topic 205-40, *Presentation of Financial Statements - Going Concern*, in order to determine whether there is substantial doubt about our ability to continue as a going concern for one year after the date our financial statements are issued. Based on the current cash forecast, management has determined that our present capital resources will not be sufficient to fund our planned operations for at least one year from the issuance date of the financial statements, which raises substantial doubt as to our ability to continue as a going concern.

The forecast of cash resources is forward-looking information that involves risks and uncertainties, and our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, slower and/or faster than expected progress of our research and development efforts, changes in governmental regulation, competitive and technical advances, rising costs associated with the development of our product candidates, our ability to secure partnering arrangements, and costs of filing, prosecuting, defending and enforcing our intellectual property rights. Global political and economic events, including the COVID-19 pandemic and increased inflation, have already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital or make the terms of any available financing less attractive, which could in the future negatively affect our operations. If we exhaust our capital reserves more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We need to raise additional capital to fund our operations. The manner in which we raise any additional funds may affect the value of your investment in our common stock.

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. We do not have any committed external source of funds. The unpredictability of the capital markets may severely hinder our ability to raise capital within the time periods needed or on terms we consider acceptable, if at all. In particular, a decline in the market price of our common stock could make it more difficult for us to sell equity or equity-related securities in the

future at a time and price that we deem appropriate. Moreover, if we fail to advance one or more of our current product candidates into early or later-stage clinical trials, successfully commercialize one or more of our product candidates, or acquire new product candidates for development, we may have difficulty attracting investors that might otherwise be a source of additional financing.

On August 6, 2021, we entered into a Loan and Security Agreement, or the Loan and Security Agreement, with Silicon Valley Bank and certain of its affiliates, or SVB. The Loan and Security Agreement provided for an initial term loan of $25.0 million funded at the closing, with an additional tranche of $25.0 million available if certain funding and clinical milestones were met by August 31, 2022, or the SVB Facility. In connection with the initial borrowing, we also issued warrants to SVB for the purchase of up to 432,844 shares of our common stock, in the aggregate, at an exercise price of $2.22 per share. The Loan and Security Agreement was subsequently amended, or the Amended Loan and Security Agreement, effective December 28, 2021, to, among other things, eliminate the additional tranche so that the $25.0 million we have drawn down is the full amount available under the SVB Facility. As a result, we do not have any other borrowings available under the SVB Facility. In connection with entering into the Amended Loan and Security Agreement we also amended and restated the warrants. These amended and restated warrants provide for the purchase of up to 649,615 shares of our common stock, in the aggregate, at an exercise price of $1.16 per share. The Amended Loan and Security Agreement also required us to cash collateralize half of the sum of the then-outstanding principal amount of the SVB Facility, plus an amount equal to 5.75% of the original principal amount of the SVB Facility in the event we failed to achieve certain equity raise and clinical milestones by August 31, 2022. We did not achieve these milestones and, as a result, deposited $13.9 million in a collateral account with SVB as required by the terms of the Amended Loan and Security Agreement. The collateralized cash represents a significant portion of our cash and cash equivalents that we are not able to access to fund our operations and is classified as restricted cash on our Balance Sheet.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, creating liens, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

We have incurred indebtedness that could adversely affect our business and place restrictions on our operating and financial flexibility.

The Amended Loan and Security Agreement contains customary affirmative and negative covenants and events of default applicable to us and any subsidiaries. The affirmative covenants require us (and us to cause our subsidiaries, if any) to maintain governmental approvals, deliver certain financial reports, maintain insurance coverage and protect material intellectual property, among other things. The negative covenants restrict our and our subsidiaries' ability to, among other things, transfer collateral, change our business, engage in mergers or acquisitions, incur additional indebtedness, pay cash dividends or make other distributions, make investments, create liens, sell assets and make any payment on subordinated debt. The restrictive covenants of the Amended Loan and Security Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial, including entering into certain licensing arrangements, maintaining flexible cash management arrangements and engaging in certain change in control transactions, among others.

Our debt combined with our other financial obligations and contractual commitments could have significant adverse consequences for our business, including:

- Requiring us to dedicate a substantial portion of cash flows to payment on our debt, which would reduce available funds for further research and development;
- Increasing the amount of interest that we must pay on debt with variable interest rates, if market rates of interest increase;
- Subjecting us to restrictive covenants that reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing; and
- Requiring us to pledge our non-intellectual property assets as collateral, which could limit our ability to obtain additional debt financing.

We intend to satisfy our debt service obligations with our existing cash and cash equivalents and any additional amounts we may raise through future debt and equity financings. Our ability to make payments due under the SVB Facility depends on our future performance, which is subject to economic, financial, competitive conditions and other factors beyond our control. We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. In addition, the Amended Loan and Security Agreement requires us to deposit unrestricted and unencumbered cash equal to 50% of the principal amount of the SVB Facility then outstanding and an amount equal to 5.75% of the original principal amount in a cash collateral account with SVB. As of December 31, 2022 we have $13.9 million in cash deposited in the cash collateral account pursuant to the terms of the Amended Loan and Security Agreement. Failure to pay any amount due under the SVB Facility, to comply with covenants under the Amended Loan and Security Agreement, or the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations or condition (financial or otherwise), would result in an event of default. The occurrence and continuation of an event of default could cause interest to be charged at the

rate that is otherwise applicable plus 3.00% (unless SVB elects to impose a smaller increase) and would provide SVB with the right to accelerate all obligations under the SVB Facility and exercise remedies against us and the collateral securing the SVB Facility and other obligations under the Amended Loan and Security Agreement, including foreclosure against assets securing the SVB Facility. In addition, the covenants under the Amended Loan and Security Agreement and the pledge of substantially all of our assets, excluding our intellectual property (which is subject to a negative pledge under the Amended Loan and Security Agreement), as collateral on the loan may limit our ability to obtain additional debt financing.

We have previously identified material weaknesses in our internal control, all of which have been remediated. We may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or could have a material adverse effect on our business and trading price of our securities.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the Nasdaq Global Select Market. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting. We may also be required to have our independent registered public accounting firm issue an opinion on the effectiveness of our internal control over financial reporting on an annual basis.

We have identified material weaknesses in our internal control over financial reporting in the past. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

Although the material weaknesses identified in the past have been remediated, we cannot assure you that any measures we have taken or may take in the future will be sufficient to avoid potential future material weaknesses. If we are unable to successfully remediate any future material weakness and maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results in future periods, or report them within the timeframes required by the requirements of the SEC, Nasdaq or the Sarbanes-Oxley Act. Failure to comply with the Sarbanes-Oxley Act, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in the identification of additional material weaknesses or significant deficiencies, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

Our plans to develop and commercialize non-viral adoptive TCR-T cell therapies can be considered a new approach to cancer treatment, the successful development of which is subject to significant challenges.

We are employing technologies such as the technology licensed from MD Anderson pursuant to the MD Anderson License described above, from PGEN, pursuant to the License Agreement, and from the NCI, pursuant to the Patent License described above, to pursue the development and commercialization of non-viral cellular therapies based on T-cells and TCRs, targeting solid tumor malignancy. Because this is a new approach to cancer immunotherapy and cancer treatment generally, developing and commercializing product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities that have very limited experience with the commercial development of genetically modified T-cell therapies for cancer;
- designing and conducting our clinical trials using this new approach or selecting the appropriate TCRs in a way that may lead to optimal results;
- identifying and manufacturing appropriate TCRs from either a patient or third parties that can be administered to the patient;
- developing and deploying consistent and reliable processes for engineering a patient's and/or donor's T cells ex vivo and infusing the T cells back into the patient;
- conditioning patients with chemotherapy in conjunction with delivery of the potential products, which may increase the risk of adverse side effects of the chemotherapy itself or of the potential products;
- educating medical personnel regarding the potential side effect profile of each of the potential products, such as the potential adverse side effects related to cytokine release;
- addressing any competing technological and market developments;
- developing processes for the safe administration of these potential products, including long-term follow-up for all patients who receive the potential products;

- sourcing additional clinical and, if approved, commercial supplies for the materials used to manufacture and process the potential products;
- developing a manufacturing process with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance;
- developing therapies for types of cancers beyond those addressed by the current potential products;
- maintaining and defending the intellectual property rights relating to any products we develop; and
- not infringing the intellectual property rights, in particular, the patent rights, of third parties, including competitors, such as those developing T-cell therapies.

We cannot assure you that we will be able to successfully address these challenges, which could prevent us from achieving our research, development and commercialization goals.

Our current product candidates are based on novel technologies and are supported by limited clinical data and we cannot assure you that our current and planned clinical trials will produce data that supports regulatory approval of one or more of these product candidates.

Our genetically modified TCR-T cell product candidates are supported by limited clinical data, some of which has been generated through trials conducted by MD Anderson and the NCI, rather than solely by us. We have assumed control of the overall clinical and regulatory development of our TCR-T cell product candidates, and any failure to obtain, or delays in obtaining, sponsorship of new INDs, or in filing INDs sponsored by us for these or any other product candidates we decide to advance could negatively affect the timing of our potential future clinical trials. Such an impact on timing could increase research and process development costs and could delay or prevent obtaining regulatory approval for our product candidates, either of which could have a material adverse effect on our business. We began enrolling patients in our TCR-T Library Phase 1/2 Trial in January 2022.

Further, we did not control the design or conduct of all of the previous trials. It is possible that the FDA will not accept these previous trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any of one or more reasons, including the safety, purity and potency of the product candidate, the degree of product characterization, elements of the design or execution of the previous trials or safety concerns or other trial results. We may also be subject to liabilities arising from any treatment-related injuries or adverse effects in patients enrolled in these previous trials. As a result, we may be subject to unforeseen third-party claims and delays in our potential future clinical trials. We may also be required to repeat in whole or in part clinical trials previously conducted by MD Anderson or other entities, which will be expensive and delay the submission and licensure or other regulatory approvals with respect to any of our product candidates.

Moreover, there are a number of regulatory requirements that we must continue to satisfy as we conduct our clinical trials of TCR-T cell product candidates in the United States. The criteria these regulators use to determine 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 and change frequently. Satisfaction of these requirements will entail substantial time, effort and financial resources. To date, the FDA has approved only a few adoptive cell therapies for commercialization. Because adoptive cell therapies are relatively new and our product candidates employ novel gene expression and cell technologies, regulatory agencies may lack experience in evaluating product candidates like our Library TCR-T product candidates. This novelty may heighten regulatory scrutiny of our therapies or lengthen the regulatory review process, including the time it takes for the FDA to review our IND applications if and when submitted, increase our development costs and delay or prevent commercialization of our product candidates. These factors make it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates. Any time, effort and financial resources we expend on our clinical product candidates and other early-stage product development programs that are ultimately not successful may adversely affect our business.

We report interim data on certain of our clinical trials and we cannot assure you that interim data will be predictive of either future interim results or final study results. In addition, the results ultimately obtained from our preclinical studies or other earlier clinical trials for our product candidates may not be predictive of future results.

As part of our business, we provide updates related to the development of our product candidates, which may include updates related to interim clinical trial data. We anticipate that our clinical trials will involve small patient populations and because of the small sample size, the interim results of these, and all, clinical trials may be subject to substantial variability and may not be indicative of either future interim results or final results.

We commenced enrollment in our TCR-T Library Phase 1/2 Trial in January 2022 and announced early clinical data for the first patient in September 2022 and for the first two patients in November 2022. The first two patients enrolled in our TCR-T Library Phase 1/2 Trial have been removed from the trial due to subsequent disease progression. We do not know at this stage whether patient response data from additional patients in this trial will be favorable, and initial success in clinical trials may not be indicative of results obtained when such trials are completed. Our product candidates may fail to show the desired safety and efficacy in clinical development, and we cannot assure you that the results of any future trials will demonstrate the value and efficacy of our product candidates. Even if our clinical trials are completed as planned, we cannot be certain that their results will support approval of our product candidates.

There are no approved engineered TCR-T cell immunotherapies for solid tumors. We believe our product candidates may be effective against certain solid tumors and plan to develop product candidates for use in those certain solid tumors. We cannot guarantee that our product candidates will be able to access the solid tumor or show any functionality in the solid tumor microenvironment. The cellular environment in which solid tumor cells thrive is generally hostile to T cells due to factors such as the presence of immunosuppressive cells, humoral factors and limited access to nutrients. In addition, the safety profile of our product candidates may differ in a solid tumor setting. If we are unable to make our product candidates function in solid tumors, our development plans and business will be significantly harmed.

Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. Negative differences between preliminary or interim data and final data could materially adversely affect the prospects of any product candidate that is impacted by such data updates.

In addition, the results of any preclinical studies for our product candidates may not be predictive of the results of clinical trials. For example, preclinical models as applied to cell therapy in oncology do not adequately represent the clinical setting, and thus cannot predict clinical activity nor all potential risks.

We will need to recruit, hire and retain qualified personnel and we will continue to rely on key scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

We may not be able to attract or retain qualified management and commercial, scientific, manufacturing and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on our principal scientific, regulatory and medical advisors. The loss of any of our key personnel could result in delays in product development, loss of key personnel or partnerships and diversion of management resources, which could adversely affect our operating results. We do not carry “key person” life insurance policies on any of our officers or key employees.

We face substantial competition from other biopharmaceutical companies, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.

Our TCR-T cell therapies targeting solid tumors face significant competition from multiple companies, and their collaborators, in the TCR and CAR technology space. We face competition from several companies, including 2Seventy Bio, Achilles Therapeutics, Annoca, Adaptimmune Therapeutics, Affini-T Therapeutics, ArsenalBio, Athenex, BioNTech, Bristol-Myers Squibb, Immatics, Iovance Biotherapeutics, Kite (a Gilead company), Lion TCR, Lyell Immunopharma, Medigene, Neogene Therapeutics (a member of the AstraZeneca group), NexImmune, Nurix Therapeutics, PACT Pharma, Precigen, Tactiva Therapeutics, Takara Bio, TCR^2 Therapeutics, T-Cure BioScience, T-knife Therapeutics, Triumvira Immunologics, TScan Therapeutics, Turnstone Biologics, Zelluna Immunotherapy and others. Many of these companies are either investigating TCR-T cells against germline antigens or are utilizing tumor infiltrating lymphocytes. Some are pursuing CAR-T cells for solid tumors. In contrast, we are focused on developing TCR-T cell products against neoantigens arising from somatic mutations in solid tumors.

Companies in the T-cell therapy segment that we believe to have target discovery platforms like ours include Adaptive Biotechnologies, Affini-T Therapeutics, Enara Bio, Immatics, Neogene Therapeutics (a member of the AstraZeneca group), PACT Pharma, T-knife Therapeutics, TScan Therapeutics and 3T Biosciences. Several companies, including Advaxis, Amgen, BioNTech, Geneos Therapeutics and Gritstone, are pursuing vaccine platforms to target neoantigens for solid tumors. Other companies are developing non-viral gene therapies, including Poseida Therapeutics and several companies developing CRISPR technology, including Captain T Cell and Crispr Therapeutics.

Several companies are pursuing the development of allogeneic CAR-T therapies, including Allogene Therapeutics, Atara Biotherapeutics and Precision Biosciences, which may compete with our product candidates. We also face competition from companies developing therapies using cells other than T cells, such as Athenex, Fate Therapeutics, ImmunityBio, IN8bio, Nkarta Therapeutics and Takeda Pharmaceutical. Other competitors are developing T cells with cytokines, such as Fate Therapeutics and Obsidian Therapeutics. Finally, we also face competition from non-cellular treatments offered by other companies, such as Amgen, AstraZeneca, Bristol-Myers Squibb, Immatics, Immunocore, Incyte, Merck, Mirati and Roche. Additionally, our ability to find partnerships relating to our IL-12 and CAR-T programs may be impacted by substantial competition from these and other biopharmaceutical companies.

Even if we obtain regulatory approval of potential TCR products, we may not be the first to market and that may affect the price or demand for our potential products. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication, or fewer side effects, than our potential products or may offer comparable performance at a lower cost. Additionally, the availability and price of our competitors’ products could limit the demand and the price we are able to charge for our potential products, thereby reducing or eliminating our commercial opportunity. We may not be able to implement our business plan if the acceptance of our potential products is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our potential products, or if physicians switch to other new drug or biologic products or choose to reserve our potential products. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor’s product. If such competitor product is determined to be the same product as one of our potential products, that may prevent us from obtaining approval from the FDA for such potential products for

the same indication for seven years, except in limited circumstances. If our potential products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have products already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs and biopharmaceuticals;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs and biopharmaceuticals;
- formulating and manufacturing drugs and biopharmaceuticals; and
- launching, marketing and selling drugs and biopharmaceuticals.

Our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Any termination of our licenses with PGEN, MD Anderson or the National Cancer Institute or our research and development agreements with MD Anderson and the National Cancer Institute could result in the loss of significant rights and could harm our ability to develop and commercialize our product candidates.

We are dependent on patents, know-how and proprietary technology that are licensed from others, particularly MD Anderson, PGEN and the NCI, as well as the contributions by MD Anderson under our research and development agreements. Any termination of these licenses or research and development agreements could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Disputes may also arise between us and these licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the applicable license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes, and the technology and processes of PGEN, MD Anderson, the NCI and our other licensors, infringe intellectual property of the licensor that is not subject to the applicable license agreement;
- our right to sublicense patent and other rights to third parties pursuant to our relationships with our licensors and partners;
- whether we are complying with our diligence and payment obligations with respect to the use of the licensed technology in relation to our development and commercialization of our potential products under the MD Anderson License, the License Agreement with PGEN and the Patent License with the NCI;
- whether or not our partners are complying with all of their obligations to support our programs under licenses and research and development agreements; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements, particularly with MD Anderson, PGEN and the NCI, on acceptable terms, we may be unable to successfully develop and commercialize the affected potential products. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize potential products under our applicable licenses could suffer. 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 and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. Recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented, which adds uncertainty to the possibility of challenge to our or our licensors' patents in the future.

We may not be able to retain the rights licensed to us and PGEN by MD Anderson or the rights licensed to us by the National Cancer Institute to technologies relating to TCR-T cell therapies and other related technologies.

Under the MD Anderson License, we, together with PGEN, received an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson including technologies relating to novel CAR-T cell and TCR-T cell therapies as well as either co-exclusive or non-exclusive licenses under certain related technologies. These proprietary methods and technologies, along with others within PGEN's technology suite and licensed to us by PGEN, may help realize the promise of genetically modified TCR-T cell therapies by controlling cell expansion and activation in the body, minimizing off-target and unwanted on-target effects and toxicity while maximizing therapeutic efficacy.

The term of the MD Anderson License expires on the last to occur of (a) the expiration of all patents licensed thereunder or (b) the twentieth anniversary of the date of the MD Anderson License; provided, however, that following the expiration of the term, we and PGEN shall then have a fully-paid up, royalty free, perpetual, irrevocable and sublicensable license to use the licensed intellectual property thereunder.

After 10 years from the date of the MD Anderson License and subject to a 90-day cure period, MD Anderson will have the right to convert the MD Anderson License into a non-exclusive license if we and PGEN are not using commercially reasonable efforts to commercialize the licensed intellectual property on a case-by-case basis. After five years from the date of the MD Anderson License and subject to a 180-day cure period, MD Anderson will have the right to terminate the MD Anderson License with respect to specific technology(ies) funded by the government or subject to a third-party contract if we and PGEN are not meeting the diligence requirements in such funding agreement or contract, as applicable. MD Anderson may also terminate the agreement with written notice upon material breach by us or PGEN, if such breach has not been cured within 60 days of receiving such notice. In addition, the MD Anderson License will terminate upon the occurrence of certain insolvency events for both us or PGEN and may be terminated by the mutual written agreement of us, PGEN and MD Anderson.

Under the Patent License, we received an exclusive, worldwide license to certain intellectual property and patents from NCI for TCRs we can introduce into T cells using transposon-based genetic engineering. These T cells may be used in our TCR-T Library Phase 1/2 Trial or in subsequent clinical trials, if initiated. The term of the Patent License shall expire with the last of the licensed patents. The NCI could terminate or modify the Patent License if it believes we have materially breached the Patent License, including by failing to meet the defined milestones by the required dates, and have not cured such breach within 90 days of receiving notice of such alleged breach. The NCI may also terminate the Patent License immediately upon our receipt of written notice of certain insolvency events. The Patent License is also subject to certain public use requirements wherein the NCI could require us to sublicense certain product candidates or terminate or modify the Patent License if we do not meet these public use requirements. The Patent License could also be terminated by the NCI if we are unable to pay the required benchmark payments or the annual minimum royalty payments.

There can be no assurance that we will be able to successfully perform under the MD Anderson License or the Patent License and if the MD Anderson License or the Patent License is terminated it may prevent us from achieving our business objectives.

We are partly reliant on the National Cancer Institute for research and development and early clinical testing of certain of our product candidates.

A portion of our research and development is being conducted by the NCI under the CRADA entered into in January 2017 and which was amended in March 2018, February 2019, March 2022 and June 2022. Under the CRADA, the NCI, with Dr. Steven A. Rosenberg as the principal investigator, is responsible for conducting a clinical trial using the *Sleeping Beauty* system to express TCRs for the treatment of solid tumors. We have limited control over the nature or timing of the NCI's clinical trial and limited visibility into their day-to-day activities, including with respect to how they are providing and administering T-cell therapy. For example, the research we are funding constitutes only a small portion of the NCI's overall research. Additionally, other research being conducted by Dr. Rosenberg may at times receive higher priority than research on our program. The progress and timeline, including the timeline for dosing patients, for this trial are under the control of the NCI.

The CRADA expired by its terms on January 9, 2022. In March 2022, we entered into an amendment to the CRADA that is retroactive, effective January 9, 2022 to extend the term of the CRADA until January 9, 2023. In June 2022, we entered into the Fourth Amendment to the CRADA, or the CRADA Fourth Amendment, which, among other things, extended the term of the CRADA until January 9, 2025. In connection with the CRADA Fourth Amendment, we agreed to contribute $1.0 million per year, payable on a quarterly basis, beginning in the first quarter of 2023.

We may not be able to commercialize any products, generate significant revenues, or attain profitability.

To date, none of our product candidates have been approved for commercial sale in any country. The process to develop, obtain regulatory approval for and commercialize potential product candidates is long, complex and costly. Unless and until we receive approval from the FDA and/or other foreign regulatory authorities for our product candidates, we cannot sell our products and will not have product revenues. Even if we obtain regulatory approval for one or more of our product candidates, if we are unable to successfully commercialize our products, we may not be able to generate sufficient revenues to achieve or maintain profitability or to continue our business without raising significant additional capital, which may not be available. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

Our operating history makes it difficult to evaluate our business and prospects.

We have not previously completed any pivotal clinical trials, submitted a BLA or demonstrated an ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- Continuing to undertake preclinical development and clinical trials;
- Participating in regulatory approval processes;

- Formulating and manufacturing products; and
- Conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary product candidates and undertaking preclinical and clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We may not be successful in establishing development and commercialization collaborations, which failure could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Developing biopharmaceutical products and complementary technologies, conducting clinical trials, obtaining marketing approval, establishing manufacturing capabilities and marketing approved products is expensive, and therefore, we anticipate exploring collaborations with third parties that have alternative technologies, more resources and more experience than we do. In situations where we enter into a development and commercial collaboration arrangement for a product candidate or complementary technology, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaboration arrangement for such product candidate or technology. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on reasonable and acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in some or all of the territories outside of the United States where it may otherwise be valuable to do so.

We may not be able to successfully manage our growth as we expand our development and regulatory capabilities, which could disrupt our operations.

As we advance our product candidates to the point of, and through, clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide for these capabilities. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel with expertise in preclinical and clinical research and testing, manufacturing, government regulation and eventually sales and marketing.

Our business will subject us to the risk of liability claims associated with the use of hazardous materials and chemicals.

Our contract research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could have a materially adverse effect on our business, financial condition, and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require our contractors to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability, and we will face an even greater risk if we commercially sell any medicines that we may develop. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products, if approved. Even a successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

- Decreased demand for our product candidates;
- Injury to our reputation;
- Withdrawal of clinical trial participants;
- Initiation of investigations by regulators;
- Withdrawal of prior governmental approvals;
- Costs of related litigation;
- Substantial monetary awards to patients;
- Product recalls;

- Loss of revenue;
- The inability to commercialize our product candidates; and
- A decline in our share price.

Although we currently carry clinical trial insurance and product liability insurance which we believe to be reasonable, it may not be adequate to cover all liability that we may incur. An inability to renew our policies or to obtain sufficient insurance at an acceptable cost could prevent or inhibit the commercialization of pharmaceutical products that we develop, alone or with collaborators.

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

Our operations, and those of our clinical investigators, contractors and consultants, are based primarily in Houston, Texas. These operations could be subject to power shortages, telecommunications failures, water shortages, hurricanes, floods, earthquakes, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we maintain customary insurance policies that we believe are appropriate. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to manufacture clinical supplies of our product candidates could be disrupted if our own operations or those of our suppliers are affected by a man-made or natural disaster or other business interruption. We may have limited recourse against third parties if the non-compliance is due to factors outside of the manufacturer's control.

We may be unable to find appropriate partners to continue the development of the product candidates we de-prioritized in 2021, which may prevent us from ever deriving meaningful revenue from them.

In 2021, we elected to prioritize our Library TCR-T program and significantly reduced our activities in connection with our Controlled IL-12 and CAR-T programs to preserve our capital resources. The decision to significantly reduce activities for our Controlled IL-12 and CAR-T programs may negatively impact the potential for these programs, which could have a material adverse effect on our business. We are actively exploring partnership opportunities for our Controlled IL-12 and CAR-T programs to support their continued development. If we are unable to identify an appropriate strategic partner or to negotiate and consummate a license or sale agreement with such a partner, it will be difficult to advance the development of these two programs, increasing the likelihood that we may be unable to derive any meaningful revenue from these assets.

We have also mutually agreed with TriArm Therapeutics Ltd., or TriArm, to dissolve the Eden BioCell joint venture. The joint venture agreement has been terminated and the Eden BioCell entity is in the process of being dissolved.

Our business, operations and clinical development plans and timelines could be adversely affected by the effects of health epidemics, including the COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in our manufacturing operations or the operations of third-party manufacturers, CROs and other third parties upon whom we rely or may rely on in the future.

We depend on a worldwide supply chain to manufacture products used in our preclinical studies and clinical trials. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at our own manufacturing facilities or third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and our ongoing TCR-T Library Phase 1/2 Trial at MD Anderson have been, and may continue to be, affected by the COVID-19 pandemic. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, have been, and may continue to be, delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, if we are unable to successfully recruit and retain patients, principal investigators, and site staff who, as healthcare providers, may have heightened exposure to COVID-19 or experience additional restrictions by their institutions, city, or state, our clinical trial operations could be adversely impacted.

RISKS RELATED TO THE CLINICAL TESTING, GOVERNMENT REGULATION AND MANUFACTURING OF OUR PRODUCT CANDIDATES

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

We have experienced, and may continue to experience, difficulties in patient enrollment in our ongoing TCR-T Library Phase 1/2 Trial and any future clinical trials, for a variety of reasons, including impacts that have resulted or may result from the COVID-19 pandemic. The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

- The patient eligibility criteria defined in the clinical trial protocol;
- The size of the patient population required for analysis of the clinical trial's primary endpoints;
- The proximity of patients to clinical trial sites;
- The number of clinical trial sites;
- The design of the clinical trial;
- Our ability to recruit and retain clinical trial investigators with the appropriate competencies and experience;
- Our ability to obtain and maintain patient consents;
- Reporting of the preliminary results of any of our clinical trials;
- Patient insurance approvals of trial participation; and
- The risk that patients enrolled in clinical trials will drop out of the clinical trials before the manufacturing and infusion of our product candidates or clinical trial completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some of our potential patients may instead opt to enroll in a clinical trial being conducted by one of our competitors. In addition, patients may be unwilling to participate in our studies because of negative publicity from adverse events in the biotechnology industry or for other reasons. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic stem cell transplantation, rather than enroll patients in any future clinical trial. Additionally, because our clinical trial is in, and our future clinical trials may be in, patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial, which would require additional patient enrollment.

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

Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. The process of obtaining regulatory approval is expensive and often takes many years following the commencement of clinical trials. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective, or with respect to a biological product candidate, safe, pure and potent, for their intended uses.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- Such authorities may disagree with the design or implementation of our or our current or future collaborators' clinical trials;

- Negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- Serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs or biologics similar to our therapeutic product candidates;
- Such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- We, or any of our current or future collaborators, may be unable to demonstrate that a product candidate is safe and effective, and that the therapeutic product candidate's clinical and other benefits outweigh its safety risks;
- We may be unable to demonstrate to the satisfaction of such authorities that our companion diagnostics are suitable to identify appropriate patient populations;
- Such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- Such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA, NDA, premarket approval, or PMA, or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- Such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- Approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- Such authorities may find deficiencies in the manufacturing processes, test procedures and specifications or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies;
- Regulations and approval policies of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- Such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we obtain regulatory approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request and may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS.

Events raising questions about the safety of certain marketed biopharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs or biologics based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

We are very early in our development efforts. Our most advanced product candidates are only in an early-stage clinical trial, which is very expensive and time-consuming. We cannot be certain when we will be able to submit a BLA to the FDA and any failure or delay in completing clinical trials for our product candidates could harm our business.

Our product candidates are in various stages of development and require extensive clinical testing. Our most advanced product candidates are in our TCR-T Library Phase 1/2 Trial, which is currently enrolling and dosing patients. Human clinical trials are very expensive and difficult to design, initiate and implement, in part because they are subject to rigorous regulatory requirements. Notwithstanding our current clinical trial plans for each of our existing product candidates, which we estimate will take several years to complete, we may not be able to commence additional trials or see results from these trials within our anticipated timelines. Failure can occur at any stage of a clinical trial, and we can encounter problems that cause us to delay the start of, abandon or repeat clinical trials. Some factors which may lead to a delay in the commencement or completion of our clinical trials include: requests for additional nonclinical data from regulators, unforeseen safety issues, dosing issues, lack of effectiveness during clinical trials, difficulty recruiting or monitoring patients, or difficulty manufacturing clinical products, among other factors.

As they enter later stages of development, our product candidates generally will become subject to more stringent regulatory requirements, including the FDA's requirements for chemistry, manufacturing and controls for product candidates entering Phase 3 clinical trials. There is no guarantee the FDA will allow us to commence Phase 3 clinical trials for product candidates studied in earlier clinical trials.

If the FDA does not allow our product candidates to enter later stage clinical trials or requires changes to the formulation or manufacture of our product candidates before commencing Phase 3 clinical trials, our ability to further develop, or seek approval for, such product candidates may be materially impacted. As such, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval of our

product candidates or whether such a BLA will be accepted. Because we do not anticipate generating revenues unless and until we submit one or more BLAs and thereafter obtain requisite FDA approvals, the timing of our BLA submissions and FDA determinations regarding approval thereof will directly affect if and when we are able to generate revenues.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any potential marketing approval.

As with many pharmaceutical and biological products, treatment with our product candidates may produce undesirable side effects or adverse reactions or events, including potential adverse side effects related to cytokine release. If our product candidates or similar products or product candidates under development by third parties demonstrate unacceptable adverse events, we may be required to halt or delay further clinical development of our product candidates. The FDA or other foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. If a serious adverse event were to occur in our TCR-T Library Phase 1/2 Trial, the FDA may place a hold on the clinical trial.

The product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, particularly outside of the institutions that collaborate with us, as toxicities resulting from our novel technologies may not be normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand their side effect profiles, both for our planned clinical trials and upon any commercialization of any product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in adverse effects to patients, including death. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the product's label;
- we may be required to create a risk evaluation and mitigation strategy plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved. Furthermore, any of these occurrences may harm our business, financial condition and prospects significantly.

Our cellular therapy immuno-oncology product candidates rely on the availability of reagents, specialized equipment and other specialty materials and infrastructure, 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, including DNA plasmids, which are used as the vector to insert our TCRs into human T cells. Some of these suppliers may not have the capacity to support commercial products manufactured under current good manufacturing practices by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with some 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, infrastructure 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, or source product on commercially reasonable terms, which could be due to, among other things, regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, supply chain issues or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our ability to conduct clinical trials, which could significantly harm our business.

In addition, some of the reagents and products used by us may be stored at a single vendor. The loss of materials located at a single vendor, or the failure of such a vendor to manufacture clinical product in accordance with our specifications, would impact our ability to conduct ongoing or planned clinical trials and continue the development of our products. Further, manufacturing replacement material may be expensive and require a significant amount of time, which may further impact our clinical programs.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain additional rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to maintain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and/or commercialization plans. If such a change occurs for a product candidate that is already in clinical trials, the change may require us to perform both ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

Because we are dependent, at least in part, upon clinical research institutions and other CROs for clinical testing and/or for research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.

We materially rely upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials under agreements with us. In addition, we hire CROs to help us manage clinical trials, collect data and analyze clinical samples. These collaborators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our product development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new products, if any, will be delayed. These institutions may also have, or implement in the future, policies and procedures that limit their ability to advance our programs. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors to our detriment, our competitive position would be harmed.

We have limited experience producing and supplying our product candidates. We may be unable to consistently manufacture our product candidates to the necessary specifications or in quantities necessary to treat patients in our clinical trials.

We have limited experience in biopharmaceutical manufacturing. In 2021, we began manufacturing our product candidates at our in-house current good manufacturing practices, or cGMP, manufacturing facility at our leased headquarters in Houston, Texas. Our ability to manufacture our product candidates depends on our finding and retaining personnel with the appropriate background and training to staff and operate the facility on a daily basis. Should we be unable to find or retain these individuals, we may need to train additional personnel to fill the needed roles or engage with external contractors. There are a small number of individuals with experience in cell therapy and the competition for these individuals is high.

Specifically, the operation of a cell-therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals who have successful previous experience in cleanroom environments. Cell therapy facilities, like other biological agent manufacturing facilities, require appropriate commissioning and validation activities to demonstrate that they operate as designed. Additionally, each manufacturing process must be proven through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. Although we have developed our own manufacturing processes using an in-house team, there is timing risk associated with increased in-house product manufacture.

The manufacture of our product candidates is complex and 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 out and validating initial production and ensuring the absence of contamination. These include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of product candidates or in our manufacturing facilities, the manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. It is possible that stability or other issues relating to the manufacture of our product candidates could occur in the future. We recently amended our clinical trial IND to use cryopreservation-based storage of clinical products. This process is new and we may experience manufacturing failures or difficulties producing sufficient quantities of our clinical products as a result of this change.

Our product candidates currently are, and will continue to be, manufactured on a patient-by-patient basis. Delays in manufacturing could adversely impact the treatment of each patient and may discourage participation in our current or future clinical trials. We have not yet manufactured our clinical trial product candidates on a large scale and may not be able to achieve large scale clinical trial or commercial manufacturing and processing on our own to satisfy expected clinical trial or commercial demands for any of our product candidates. While we believe that our current manufacturing and processing approaches are appropriate to support our early-stage clinical product development, we have limited experience in managing the T cell engineering process, and our processes may be more difficult or more expensive than anticipated. The manufacturing processes employed by us may not result in product candidates that will be safe and effective. If we are unable to manufacture sufficient number of TCR-T cells for our product candidates, our development efforts would be delayed, which would adversely affect our business and prospects.

Our manufacturing operations are subject to review and oversight by the FDA. We are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations. Our license to manufacture product candidates is subject to continued regulatory review.

We do not yet have sufficient information to reliably estimate the cost of commercial manufacturing and processing of our product candidates. The actual cost to manufacture and process our product candidates at commercial scale could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

We also may fail to manage the logistics of collecting and shipping patient material to our manufacturing site and shipping the product candidate back to the patient. Logistical and shipment delays and problems, whether or not caused by us or our vendors, could prevent or delay the delivery of product candidates to patients.

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

During our development of the manufacturing process, our TCR-T cell product candidates have demonstrated consistency from lot to lot and from donor to donor. However, our sample size is small and the starting material used during our preclinical development work came from healthy donors. As we work with white blood cells taken from our patient population, we may encounter unforeseen difficulties due to starting with material from donors who are not healthy, including challenges inherent in harvesting white blood cells from unhealthy patients.

Although we believe our current manufacturing process is scalable for our clinical development and commercialization, if any of our product candidates are approved or commercialized, we may encounter challenges in validating our process due to the heterogeneity of the product starting material. However, we anticipate that during the early phases of our clinical trials we will be able to adapt our process to account for these differences, resulting in a more robust process. We cannot guarantee that any other issues relating to the heterogeneity of the starting material will not impact our ability to commercially manufacturing our product candidates.

The gene transfer vectors from our Sleeping Beauty system used to manufacture our product candidates may incorrectly modify the genetic material of a patient's T cells, potentially triggering the development of a new cancer or other adverse events.

Our TCR-T cells are manufactured using our *Sleeping Beauty* system, a non-viral vector to insert genetic information encoding the TCR construct into the patient's T cells. The TCR construct is then primarily integrated at thymine-adenine, or TA, dinucleotide sites throughout the patient's genome and, once expressed as protein, is transported to the surface of the patient's T cells. Because the gene transfer vector modifies the genetic information of the T cell, there is a theoretical risk that modification will occur in the wrong place in the T cell's genetic code, leading to vector-related insertional oncogenesis, and causing the T cell to become cancerous. If the cancerous T cell is then administered to the patient, the cancerous T cell could trigger the development of a new cancer in the patient. We use non-viral vectors to insert genetic information into T cells, which we believe have a lower risk of insertional oncogenesis as opposed to viral vectors. However, the risk of insertional oncogenesis remains a concern for gene therapy, and we cannot assure you that it will not occur in any of our ongoing or planned clinical trials. There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of the vectors used to carry the genetic material. Although we use non-viral vectors, the FDA has stated that lentiviral vectors possess characteristics that may pose high risks of delayed adverse events. If any such adverse events occur from our non-viral vector, further advancement of our preclinical studies or clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, among other things, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS, which could include requirements for a restricted distribution system. If any of our product candidates receives marketing approval, the accompanying label may limit the approved uses, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA closely regulates the post-approval marketing and promotion of products to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our products outside of their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- Litigation involving patients taking our product;
- Restrictions on such products, manufacturers or manufacturing processes;
- Restrictions on the labeling or marketing of a product;
- Restrictions on product distribution or use;
- Requirements to conduct post-marketing studies or clinical trials;
- Warning letters;
- Withdrawal of the products from the market;
- Refusal to approve pending applications or supplements to approved applications that we submit;
- Recall of products;
- Fines, restitution or disgorgement of profits or revenues;
- Suspension or withdrawal of marketing approvals;
- Damage to relationships with existing and potential collaborators;
- Unfavorable press coverage and damage to our reputation;
- Refusal to permit the import or export of our products;
- Product seizure; and
- Injunctions or the imposition of civil or criminal penalties.

Noncompliance with requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with U.S. and foreign regulatory requirements regarding the development of products for pediatric populations and the protection of personal health information can also lead to significant penalties and sanctions.

RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

If we are unable to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, our business will suffer.

We may not be able to obtain the approvals necessary to commercialize our product candidates, or any product candidate that we may acquire or develop in the future for commercial sale. We will need FDA approval to commercialize our product candidates in the United States and approvals from regulatory authorities in foreign jurisdictions equivalent to the FDA to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a BLA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the product candidate, and will require substantial resources for research, development and testing. We cannot predict whether our research, development and clinical approaches will result in products that the FDA will consider safe for humans and effective for their intended uses. The FDA has substantial discretion in the approval process and may require us to conduct additional preclinical studies and clinical trials or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- Delay commercialization of, and our ability to derive product revenues from, our product candidates;
- Impose costly procedures on us; and
- Diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our BLAs. We cannot be sure that we will ever obtain regulatory approval for any of our product candidates. Failure to obtain FDA approval for our product candidates will severely undermine our business by leaving us without a marketable product, and therefore without any potential revenue source, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate or that we will obtain FDA approval if we are able to do so.

In foreign jurisdictions, we similarly must receive approval from applicable regulatory authorities before we can commercialize any of our product candidates. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize our product candidates successfully.

We currently have no marketing, sales or distribution capabilities. If and when we become reasonably certain that we will be able to commercialize our current or future product candidates, we anticipate allocating resources to the marketing, sales and distribution of our proposed products in North America and in certain other geographies; however, we cannot assure that we will be able to market, sell, and distribute our products successfully. Our future success also may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities and to encourage the collaborator's strategic interest in the product candidates under development, and such collaborator's ability to successfully market and sell any such products. Although we intend to pursue certain collaborative arrangements regarding the sale and marketing of certain of our product candidates, there are no assurances that we will be able to establish or maintain collaborative arrangements or, if we are able to do so, whether we would be able to conduct our own sales efforts. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product candidates in the United States or overseas.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would harm our business. If we rely on pharmaceutical or biotechnology companies with established distribution systems to market our products, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms or at all. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties that may not be successful and that will be only partially in our control.

If physicians and patients do not accept and use our product candidates, once approved, our ability to generate revenue from sales of our products will be materially impaired.

Even if the FDA and/or foreign equivalents thereof approve our product candidates, physicians and patients may not accept and use them. The use of engineered T cells as potential cancer treatments is a relatively recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community. Acceptance and use of our products will depend upon a number of factors, including:

- The clinical indications for which our product candidates are approved;
- Perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- The prevalence and severity of any side effects;
- Pharmacological benefit and cost-effectiveness of our products relative to competing products;
- Relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- Availability of coverage and adequate reimbursement for our products from government or other third-party payors;
- Effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any; and
- The price at which we sell our products.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of a product to find market acceptance would harm our business and could require us to seek additional financing in order to fund the development of future product candidates. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Our ability to generate product revenues will be diminished if our products do not obtain coverage and adequate reimbursement from payors.

Our ability to commercialize our product candidates, if approved, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement will be available from third-party payors, including government and health administration authorities, private health maintenance organizations and health insurers and other payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Sufficient coverage and adequate reimbursement from third-party payors are critical to new product acceptance. Coverage decisions may depend upon clinical and

economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. It is difficult to predict the coverage and reimbursement decisions that will be made by third-party payors for novel gene and cell therapy products such as ours. Even if we obtain coverage for our product candidates, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. 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.

In addition, the market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement, which might not include all of the FDA-approved drugs for a particular indication. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that would require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that approval will be obtained. If we are unable to obtain coverage of and adequate payment levels for our product candidates, if approved, from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer our products and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition and future success.

In addition, in many foreign countries, particularly the countries of the EU, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Cancer therapies are sometimes characterized as first line, second line or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates as a third line therapy for patients who have failed other approved treatments.

Subsequently, for those product candidates that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for second line or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Our market opportunities may also be limited by competitor treatments that may enter the market.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory enactments in recent years that change the healthcare system in ways that could impact our future ability to sell our product candidates profitably.

Furthermore, there have been and continue to be a number of initiatives at the federal and state level that seek to reduce healthcare costs. Most significantly, in March 2010, President Obama signed into law the ACA, which included measures that have significantly changed the way healthcare is financed by both governmental and private insurers. The ACA, among other things, imposed 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, extended the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or reformulated drugs, established annual fees on manufacturers and importers of certain branded prescription drugs and biologic agents, promoted a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program and imposed a number of substantial new compliance provisions related to pharmaceutical companies' interactions with healthcare practitioners. The ACA also expanded eligibility for Medicaid programs and introduced a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research and a new Center for Medicare & Medicaid Innovation at CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, legal and political challenges to certain aspects of the ACA. For example, President Trump signed several executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, Congress repealed the tax penalty, effective January 1, 2019, for an individual's failure to maintain ACA-mandated health insurance as part of the Tax Act. Further, President Biden issued an executive order that instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the 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 implementing a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact ACA and our business. The ultimate content, timing or effect of any healthcare reform measures on the U.S. healthcare industry is unclear.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. As a result, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals.

The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 30, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2032. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden Administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Individual states in the United States also have increasingly passed legislation and implemented 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 that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or

other healthcare reforms may prevent us from being able to generate revenue, attain profitability or, if we receive regulatory approval, commercialize our products.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. For example, we could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others:

- The federal Anti-Kickback Statute, which regulates our business activities, including our clinical research and relationships with healthcare providers or other entities as well as our future marketing practices, educational programs and pricing policies, and by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- Federal civil and criminal false claims laws, including the False Claims Act, which permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- HIPAA, which created new federal civil and criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HITECH, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities and individuals subject to the law including certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as individuals and entities that perform services for them which involve the use, or disclosure of, individually identifiable health information, known as business associates and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- Requirements under the Physician Payments Sunshine Act to report annually to CMS certain financial arrangements with prescribers and teaching hospitals, as defined in the ACA and its implementing regulations, including reporting any "transfer of value" made or distributed to teaching hospitals, and physicians, as defined by such law and reporting any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year; and
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities; state laws that require the reporting of information related to drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including any consulting agreements with physicians who may receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has further strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

To the extent that any of our product candidates is ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations.

Efforts to ensure that our business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do 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, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in United States federal or state health care programs, such as Medicare and Medicaid, disgorgement, imprisonment, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can

mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Our immuno-oncology product candidates may face competition in the future from biosimilars and/or new technologies.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, provides an abbreviated pathway for the approval of follow-on biological products. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. However, there is a risk that the U.S. Congress could amend the BPCIA to significantly shorten this exclusivity period, potentially creating the opportunity for generic competition sooner than anticipated. Further, this data exclusivity does not prevent another company from developing a product that is highly similar to the original branded product, generating its own data and seeking approval. Data exclusivity only assures that another company cannot rely upon the data within the innovator's application to support the biosimilar product's approval.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cyber security incidents, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability which could harm our ability to operate our business effectively and adversely affect our business and reputation.

In the ordinary course of our business, we, our CROs and other third parties on which we rely collect and store sensitive data, including legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business-critical information including research and development information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Any such event could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Although we have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates, we cannot guarantee that those measures will be successful in preventing any such security incident. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct research, development and commercialization activities, process and prepare Company financial information, manage various general and administrative aspects of our business and damage our reputation, in addition to possibly requiring substantial expenditures of resources to remedy, any of which could adversely affect our business. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. If the technology supporting our hunTR discovery engine were to experience a cyber-incident resulting in the disclosure or theft of our proprietary screening software or library of TCRs our business may be materially and negatively impacted. While we are not aware of any such material system failure, accident or security breach to date, 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 our research, development and commercialization efforts could be delayed.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we or our licensors fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish and our ability to successfully commercialize our products may be impaired.

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve confidential information, including trade secrets, to prevent third parties from infringing our proprietary rights, and to operate without infringing the proprietary rights of third parties.

To date, we have exclusive rights in the field of cancer treatment to certain U.S. and foreign intellectual property with respect to certain cell therapy and related technologies from MD Anderson and the NCI, as well as with respect to the PGEN technology, including *Sleeping Beauty*. Under the MD Anderson License, future patent applications require the agreement of each of MD Anderson, PGEN and us, and MD Anderson has the right to control the preparation, filing and prosecution of such patent applications unless the parties agree that we or PGEN instead may control such activities. Although under the MD Anderson License MD Anderson has agreed to review and incorporate any reasonable comments that we or PGEN may have regarding licensed patents and patent applications, we cannot guarantee that our comments will be solicited or implemented. Under the Patent License with the NCI for certain TCRs, the NCI is responsible for the preparation, filing, prosecution and maintenance of patent applications and patents licensed to us. Although under the Patent License the NCI is required to consult

with us in the preparation, filing, prosecution and maintenance of all its patent applications and patents licensed to us, we cannot guarantee that our comments will be solicited or implemented. Under our License Agreement with PGEN, PGEN has the right, but not the obligation, to prepare, file, prosecute and maintain the patents and patent applications licensed to us and shall bear all related costs incurred by it in regard to those actions. PGEN is required to consult with us and keep us reasonably informed of the status of the patents and patent applications licensed to us, and to confer with us prior to submitting any related filings and correspondence. Although under the License Agreement PGEN has agreed to consider in good faith and consult with us regarding any comments we may have regarding these patents and patent applications, we cannot guarantee that our comments will be solicited or followed. Without direct control of the in-licensed patents and patent applications, we are dependent on MD Anderson, the NCI or PGEN, as applicable, to keep us advised of prosecution, particularly in foreign jurisdictions where prosecution information may not be publicly available. We anticipate that we, the NCI and PGEN will file additional patent applications both in the United States and in other jurisdictions. However, we cannot predict or guarantee for either our in-licensed patent portfolios or for Alaunos' patent portfolio:

- When, if at all, any patents will be granted on such applications;
- The scope of protection that any patents, if obtained, will afford us against competitors;
- That third parties will not find ways to invalidate and/or circumvent our patents, if obtained;
- That others will not obtain patents claiming subject matter related to or relevant to our product candidates; or
- That we will not need to initiate litigation and/or administrative proceedings that may be costly whether we win or lose.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do 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 third parties. We may also require the cooperation of our licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of other jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, methods of therapeutic treatment, which are patent-eligible in the United States, may not be claimed in many other jurisdictions; some patent offices (such as the European Patent Office) may permit the redrafting of method of treatment claims into a "medical use" format that is patent-eligible, while other patent offices (such as the Indian Patent Office) may not accept any redrafted claiming format for such claims.

Changes in patent laws or in interpretations of patent laws in the United States and other jurisdictions may diminish the value of our intellectual property or narrow the scope of our patent protection. In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, resulting in a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In addition, the United States Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the value of patents, once obtained, and with regard to our ability to obtain patents in the future. As the USPTO continues to implement the Leahy-Smith Act, and as the federal courts have the opportunity to interpret the Leahy-Smith Act, the laws and regulations governing patents, and the rules regarding patent procurement 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.

Certain technologies utilized in our research and development programs are already in the public domain. Moreover, a number of our competitors have developed technologies, or filed patent applications or obtained patents on technologies, compositions and methods of use that are relevant to our business and may cover or conflict with our owned or licensed patent applications, technologies or product candidates. Such conflicts could limit the scope of the patents, if any, that we may be able to obtain. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases at all, and because publications of discoveries in the scientific literature lag behind actual discoveries per se, neither we nor our licensors can be certain that others have not filed patent applications for technology used by us or covered by our pending patent applications. We cannot know with certainty whether we were the first to make and file for the inventions claimed in our owned patent portfolio, or whether our licensors were the first to make and file for the inventions claimed in our in-licensed patent portfolio. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. In addition, our own earlier filed patents and applications or those of MD Anderson, the NCI or PGEN may limit the scope of later patents we obtain, if any. If third parties file or have filed patent applications or obtained patents on technologies, compositions and methods of use that are relevant to our business and that cover or conflict with our owned or licensed patent applications, technologies or product candidates, we may be required to challenge such protection, terminate or modify our programs impacted by such protection, or obtain licenses from such third parties, which might not be available on acceptable terms, or at all.

Even if our owned and licensed patent applications were to be issued as patents, they may not issue in a form that would provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity due to our patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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 even 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.

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

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, and to maintain our competitive position, we rely on trade secret protection and confidentiality agreements. To this end, it is our general policy to require our employees, consultants, advisors and contractors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how, confidential information or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. Moreover, we may not be able to obtain adequate remedies for any breaches of these agreements. Our trade secrets or other confidential information may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or other confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets or other confidential information were to be lawfully obtained or independently developed by competitors, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Third-party claims of intellectual property infringement would require us to spend significant time and money and could prevent us from developing or commercializing our products.

In order to protect or enforce patent rights, we may initiate patent infringement litigation against third parties. Similarly, we may be sued by others for patent infringement. We also may become subject to pre- and post-grant proceedings conducted in the USPTO, including interferences, derivations, post-grant review, *inter partes* review, or reexamination. In other jurisdictions, our patent estate may be subject to pre- and post-grant opposition, nullity, revocation proceedings and the like. Asserting and defending against intellectual property actions are costly and divert technical and management personnel away from their normal responsibilities.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our products or use of our products do not infringe or will not be asserted to infringe third-party patents. It is also possible that we have failed to identify relevant third-party patents or applications, or that as-yet unpublished third-party patent applications will later result in the grant of patents relevant to our business. Another possibility is for a third-party patent or patent application to first contain claims not relevant to our business but then to be reissued or amended in such a way that it does become relevant.

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be asserted to infringe patents or patent applications under which we do not hold licenses or other rights. Owning a patent does not confer on the patentee the right to practice the claimed invention and does not protect the patentee from being sued for infringement of another owner's patent. Our patent position cannot and does not provide any assurance that we are not infringing or will not be asserted to infringe the patent rights of another.

The patent landscape in the field of immuno-oncology is particularly complex. We are aware of numerous United States and foreign patents and pending patent applications of third parties directed to compositions, methods of use and methods of manufacture of immuno-oncology products. In addition, there may be patents and patent applications in the field of which we are not aware. The technology we license from MD Anderson, the NCI and PGEN is early-stage technology, and we are in the process of designing and developing products using this technology. Although we will seek to avoid pursuing the development of products that may infringe any third-party patent claims that we believe to be valid and enforceable, we may fail to do so. Moreover, given the breadth and number of claims in patents and pending patent applications in

the field of immuno-oncology and the complexities and uncertainties associated with them, third parties may allege that we are infringing patent claims even if we do not believe such claims have merit.

If a claim for patent infringement is asserted, there can be no assurance that the resolution of the claim would permit us to continue marketing the relevant product on commercially reasonable terms, if at all. We may not have sufficient resources to bring these actions to a successful conclusion. If we do not successfully defend any infringement actions to which we become a party or if we are unable to have any asserted third-party patents declared invalid or unenforceable, we may have to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, and/or we may be required to discontinue or significantly delay commercialization and development of the affected products.

Any legal action against us or our collaborators claiming damages and seeking to enjoin developmental or marketing activities relating to affected products could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain licenses to continue to develop, manufacture or market the affected products. Such licenses may not be available to us on commercially reasonable terms, or at all.

An adverse determination in a proceeding involving our owned or licensed intellectual property may allow entry in the market of substitutes, including biosimilar or generic substitutes, for our products.

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 noncompliance with these requirements.

Annuities and other similar fees must be paid to the respective patent authority to maintain patents (or patents and patent applications) in most jurisdictions worldwide. Further, patent authorities in jurisdictions worldwide require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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 submit documents with the necessary formal requirements, such as notarization and legalization. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have in-licensed patents and patent applications under the MD Anderson License, the Patent License, and the License Agreement. Under these agreements, we are subject to a range of obligations pertaining to commercialization and development, sublicensing, royalty, patent prosecution and maintenance, and insurance.

Any failure by us to obtain a needed license, comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could have a material adverse effect on our financial condition, results of operations, liquidity or business. Even if we contest any such termination or claim and are ultimately successful, such dispute could lead to delays in the development or commercialization of potential products and result in time-consuming and expensive litigation or arbitration. On termination we may be required to license to the licensor any related intellectual property that we developed.

In addition, in certain cases, the rights licensed to us are rights of a third party licensed to our licensor. In such instances, if our licensors do not comply with their obligations under such licenses, our rights under our license agreements with our licensor may be adversely affected.

In addition, the licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

OTHER RISKS RELATED TO OUR COMPANY

Our stock price has been, and may continue to be, volatile.

The market price for our common stock is volatile and may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- Price and volume fluctuations in the overall stock market;
- Changes in operating results and performance and stock market valuations of other biopharmaceutical companies generally, or those that develop and commercialize cancer drugs in particular;
- Market conditions or trends in our industry or the economy as a whole;
- Preclinical studies or clinical trial results;
- The commencement, enrollment or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- Public statements by third parties like trial participants and clinical investigators regarding our current or future clinical trials;
- Public concern as to the safety of drugs developed by us or others;
- The financial or operational projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- Comments by securities analysts or changes in financial estimates or ratings by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- The public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, as well as announcements of the status of development of our products, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements and other announcements relating to product development, litigation and intellectual property impacting us or our business;
- Government regulation;
- FDA determinations on the approval of a product candidate BLA submission;
- The sustainability of an active trading market for our common stock;
- Future sales of our common stock by us, our executive officers, directors and significant stockholders;
- Announcements of mergers or acquisition transactions;
- Our inclusion or deletion from certain stock indices;
- Developments in patent or other proprietary rights;
- Changes in reimbursement policies;
- Announcements of medical innovations or new products by our competitors;
- Announcements of changes in our senior management or directors;
- General economic, industry, political and market conditions, including, but not limited to, the ongoing impact of global economic conditions;
- Other events or factors, including those resulting from war, incidents of terrorism, natural disasters, pandemics or responses to these events; and

- Changes in accounting principles.

In addition, the stock market in general and our stock in particular from time to time experiences significant price and volume fluctuations unrelated to the operating performance of particular companies, including in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Public debt and equity markets, and in particular the Nasdaq Global Select Market, have experienced extreme price and volume fluctuations that have affected, and continue to affect, the market prices of equity securities of many biopharmaceutical companies.

Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources, and the attention of management could be diverted from our business.

Public statements made by third parties such as trial participants and clinical investigators about our current or future clinical trials without our consent may adversely impact our stock price. We may not be aware of these third-party statements when made, may not be able to respond to these third-party statements and may not be able to defend our business or the public's legitimate interests due to restrictions on what we may say about our product candidates, which may cause the price of our stock to fluctuate. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

If we fail to satisfy applicable listing standards, our common stock may be delisted from the Nasdaq Global Select Market. Delisting could prevent us from maintaining an active, liquid and orderly trading market for our common stock.

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the Nasdaq Global Select Market or if we are unable to transfer our listing to another stock market. On January 4, 2023, we were notified by The Nasdaq Stock Market LLC, or Nasdaq, that we were in breach of Listing Rule 5450(a)(1), or the Minimum Bid Price Rule, for continued listing on the Nasdaq Global Select Market because the minimum bid price of our listed securities for 30 consecutive business days had been less than $1 per share. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we have been provided a period of 180 calendar days, or until July 3, 2023, or the Compliance Date, to regain compliance with the Bid Price Requirement. If, at any time before the Compliance Date, the bid price for our common stock closes at $1.00 or more for a minimum of 10 consecutive business days as required under the Compliance Period Rule, Nasdaq will provide us written notification that we have regained compliance with the Bid Price Requirement, unless Nasdaq exercises its discretion to extend this ten-day period.

During this 180-day period, we anticipate reviewing our options to regain compliance with the Minimum Bid Price Rule, including conducting a reverse stock split. On March 2, 2023, the closing price of our common stock was $0.57 per share. If we are unable to continue to meet the requirements for listing on the Nasdaq Global Select Market we may apply to Nasdaq to list our common stock on the Nasdaq Capital Market, which may also provide us up to an additional 180 days to regain compliance with the Minimum Bid Price Rule. Nasdaq would have to accept our application to list on the Nasdaq Capital Market and we would need to show our compliance with the other listing standards and provide Nasdaq written notice of our intention to cure the Bid Price deficiency. Should Nasdaq determine that we are not eligible to list on the Nasdaq Capital Market or we elect not to submit an application to transfer to the Nasdaq Capital Market, we will receive written notice that our common stock will be delisted, at which point we will have the opportunity to appeal that decision. If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, deterring broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, the price of our common stock may decline, and although our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Further, if our common stock is delisted, we would incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our shareholders to sell our common stock in the secondary market.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and hinder a takeover attempt, and limit who may call a special meeting of stockholders. In addition, Section 203 of the Delaware General Corporation Law, or Section 203, generally prohibits a publicly held Delaware corporation from engaging in a business combination with a party that owns at least 15% of its common stock unless the business combination is approved by our board of directors before the person acquires the 15% ownership

stake or later by its board of directors and two-thirds of its stockholders. Section 203 could have the effect of delaying, deferring or preventing a change in control that our stockholders might consider to be in their best interests.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the amended and restated certificate of incorporation or our bylaws; (v) any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; or (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

These provisions 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 Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision 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.

Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at a profit.

We have never paid dividends on our common stock, and we do not anticipate that we will pay any dividends for the foreseeable future. Accordingly, any return on an investment in us will be realized, if at all, only when you sell shares of our common stock.

Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.

We have generated significant net operating loss carryforwards, or NOLs, and research and development tax credits, or R&D credits, as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years. However, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, respectively. Those sections generally restrict the use of NOLs and R&D credits after an "ownership change." An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the U.S. Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 of the Code imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carry forwards and Section 383 of the Code imposes an annual limitation on the amount of tax a corporation may offset with business credit (including R&D credits) carryforwards.

We may have experienced an "ownership change" within the meaning of Section 382 of the Code in the past and there can be no assurance that we will not experience additional ownership changes in the future. As a result, our NOLs and business credits (including R&D credits) may be subject to limitations, and we may be required to pay taxes earlier and in larger amounts than would be the case if our NOLs or R&D credits were freely usable.

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

Our business could be negatively affected as a result of the actions of activist stockholders.

In 2021, we were engaged in a consent solicitation led by WaterMill Asset Management Corp., or WaterMill, where three new directors were added to our board of directors. We could experience other stockholder activism in the future, including another consent solicitation or a proxy

contest. Activist shareholders may advocate for certain governance and strategic changes at our company. In the event of stockholder activism, particularly with respect to matters which our board of directors, in exercising their fiduciary duties, disagree with or have determined not to pursue, our business could be adversely affected because responding to actions by activist stockholders can be costly and time-consuming, disrupting our operations and diverting the attention of management, and perceived uncertainties as to our future direction may result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel, business partners, and customers.

In addition, if faced with a consent solicitation or proxy contest, we may not be able to respond successfully to the contest or dispute, which would be disruptive to our business. If individuals are elected to our board of directors with a differing agenda, our ability to effectively and timely implement our strategic plan and create additional value for our stockholders may be adversely affected.

The exercise of outstanding warrants, and issuance of equity awards may have a dilutive effect on our stock, and negatively impact the price of our common stock.

As of December 31, 2022, we had warrants for 22,922,342 shares of our common stock outstanding at a weighted average exercise price of $5.62 per share. We are able to grant stock options, restricted stock, restricted stock units, stock appreciation rights, bonus stocks, and performance awards under our 2020 Equity Incentive Plan. As of December 31, 2022, under the 2020 Equity Incentive Plan and the 2012 Equity Incentive Plan, 10,408,622 shares were issuable upon the exercise of outstanding options at a weighted average exercise price of $1.84 per share.

Our principal stockholders, executive officers and directors have substantial control over the Company, which may prevent you and other stockholders from influencing significant corporate decisions and may harm the market price of our common stock.

As of December 31, 2022, our executive officers, directors and holders of five percent or more of our outstanding common stock beneficially owned, in the aggregate, 33.2% of our outstanding common stock. These stockholders may have interests that conflict with our other stockholders and, if acting together, have the ability to influence the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- Delaying, deferring or preventing a change in control;
- Impeding a merger, consolidation, takeover or other business combination involving us; or
- Discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

In addition, this significant concentration of stock ownership may adversely affect the trading price of our common stock should investors perceive disadvantages in owning shares of common stock in a company that has such concentrated ownership.

Changes to corporate tax legislation, including the Tax Cuts and Jobs Act, signed into law in 2017, could adversely affect our business and financial condition.

The Tax Act contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, enacted in 2020, modified certain of these tax changes, and enacted other tax changes applicable to corporations. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act and the CARES Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. Currently, bills introduced in Congress, including the Build Back Better Act, contain additional changes to the taxation of corporations, which could adversely affect our business and financial condition. The impact of the Tax Act, the CARES Act and any other tax legislation on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common

stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million as of the last business day of our most recently completed second quarter if our annual revenues are $100 million or more as of our most recently completed fiscal year, or until our public float exceeds $700 million as of the last business day of our most recently completed second quarter if our annual revenues are less than $100 million as of our most recently completed fiscal year.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate office is located at 8030 El Rio Street, Houston, Texas 77054. Our Houston offices are leased pursuant to the 2019 Lease and the 2020 Lease, as described below, and comprise a total of approximately 17,265 square feet. In December 2021, we made the decision to close our former corporate office in Boston, Massachusetts. We are still party to the Boston lease and have subleased a portion of the space. We continue to seek an acceptable sublessee of the remaining portion of the Boston lease to become a subtenant and/or assume our obligations under the lease.

In October 2019, we entered into an agreement with MD Anderson to lease laboratory and office space on MD Anderson's campus, or, as amended, the 2019 Lease. We use this location to house our laboratory, cGMP clinical manufacturing facilities and office space on MD Anderson's campus. The 2019 Lease expires in February 2027. The monthly rent expense of the 2019 Lease with MD Anderson was being deducted from our prepayment at MD Anderson until the third quarter of 2021, since which time we pay MD Anderson monthly.

In December 2020, we entered into a second agreement with MD Anderson to lease additional space on MD Anderson's campus, or, as amended, the 2020 Lease. The 2020 Lease expires in April 2028 and may be extended for one additional five-year term at our election. In April 2022, we modified the 2020 Lease, which reduced our leased space from 18,111 square feet to 3,228 square feet. See Note 8 to the accompanying financial statements, *Leases,* for further details.

We believe that our existing facilities are adequate to meet our current needs.

Item 3. Legal Proceedings

In the ordinary course of business, we may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities. The results of litigation and claims cannot be predicted with certainty, and unfavorable resolutions are possible and could materially affect our results of operations, cash flows or financial position. In addition, regardless of the outcome, litigation could have an adverse impact on us because of defense costs, diversion of management resources and other factors.

We do not have any pending litigation that, separately or in the aggregate, would, in the opinion of management, have a material adverse effect on our results of operations, financial condition or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market for Common Stock

Our common stock trades on the Nasdaq Global Select Market under the symbol "TCRT."

Record Holders

As of February 15, 2023, we had approximately 240 holders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company, or DTC. Shares of common stock that are held by financial institutions as nominees for beneficial owners or in "street name" are deposited into participant accounts at DTC and are considered to be held of record by Cede & Co. as one stockholder.

Dividends

We have never declared or paid a cash dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

Unregistered Sales of Securities

We did not sell or issue any equity securities during the three months ended December 31, 2022 that were not registered under the Securities Act.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those contained in or implied by any forward-looking statements. Factors that could cause or contribute to these differences include those under "Risk Factors" included in Part I, Item 1A and under "Special Note Regarding Forward-Looking Statements" or in other parts of this Annual Report on Form 10-K.

Overview

We are a clinical-stage oncology-focused cell therapy company developing adoptive TCR-T cell therapy, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. We are leveraging our cancer hotspot mutation TCR library and our proprietary, non-viral *Sleeping Beauty* gene transfer platform to design and manufacture patient-specific cell therapies that target neoantigens arising from shared tumor-specific mutations in key oncogenic genes, including *KRAS*, *TP53* and *EGFR*. In collaboration with MD Anderson, we are currently enrolling and treating patients for a Phase 1/2 clinical trial evaluating 12 TCRs reactive to mutated *KRAS, TP53* and *EGFR* from our TCR library for the investigational treatment of non-small cell lung, colorectal, endometrial, pancreatic, ovarian and bile duct cancers, which we refer to as our TCR-T Library Phase 1/2 Trial.

As of December 31, 2022, we had approximately $53.0 million of cash, cash equivalents and restricted cash. Our restricted cash of $13.9 million relates to the Amended Loan and Security Agreement. Given our current development plans, we anticipate our cash resources will be sufficient to fund our operations into the fourth quarter of 2023, and we have no committed sources of additional capital at this time. See "*Liquidity and Capital Resources*."

We have not generated any product revenue and have incurred significant net losses in each year since our inception. For the year ended December 31, 2022, we had a net loss of $37.7 million, and through December 31, 2022, we have incurred approximately $880.6 million of accumulated deficit since our inception in 2003. We expect to continue to incur significant operating expenditures and net losses. Further development of our product candidates will likely require substantial increases in our expenses as we:

- continue to undertake clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- work with regulatory authorities to identify and address program-related inquiries;
- implement additional internal systems and infrastructure;
- hire additional personnel; and
- scale up and scale out the manufacturing of our product candidates.

We continue to seek additional financial resources to fund the further development of our product candidates. If we are unable to obtain sufficient additional capital, one or more of these programs could be delayed, and we may be unable to continue our operations at planned levels and be forced to reduce our operations. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

2022 Developments

In the fourth quarter of 2022, we submitted an IND amendment to the FDA to add two new TCRs to our clinical trial targeting frequent mutations and HLAs, with the potential to double the addressable market of our TCR-T Library Phase 1/2 Trial. The addition of these new TCRs highlights our strategy to add both more HLAs to existing mutations (KRAS-G12V and HLA-DRB1*07:01) and new mutations within our targeted gene families (TP53-R273C and HLA-DPB1*04:02). In 2023, we expect to further expand our library with exclusively owned TCRs targeting recurrent hotspot mutations in *KRAS, TP53* and *EGFR* to include 15 TCRs.

We continue to actively enroll patients in our TCR-T Library Phase 1/2 Trial targeting *KRAS, TP53* and *EGFR* hotspot mutations across six solid tumor indications. In September 2022, we announced the first objective clinical response from a TCR-T cell therapy using non-viral *Sleeping Beauty* targeting solid tumors. We successfully dosed the third patient in the trial in December 2022 and expect to enroll multiple patients in the first half of 2023. The fourth quarter IND amendment also combined our treatment and screening protocols, streamlining enrollment and potentially making it easier for both patients and physicians. The amended IND also eliminated the requirement for retesting of the tumor mutation if six months had passed between screening and treatment. We anticipate providing an interim clinical data update in 2023 as we work toward advancing the TCR-T Library Phase 1/2 Trial into Phase 2 and we expect to be Phase 2 ready by the end of 2023.

We continue to execute on our multi-pronged strategy to expand manufacturing capacity and efficiency. We doubled our manufacturing capacity in 2022 allowing for production of two products simultaneously. We also filed an IND amendment to move from fresh to cryopreserved product and expect to begin implementing this change in the first half of 2023. The use of cryopreserved cell products is

expected to reduce manufacturing process time from 30 days to 26 days, a 13% decrease, while increasing flexibility for patient scheduling and treatment. We have ongoing initiatives to optimize the process and further reduce the manufacturing time.

We are advancing our TCR-T cell therapy program towards an IND filing anticipated in the second half of 2023. We believe mbIL-15 has the potential to increase the survival of TCR-T cells in the harsh tumor microenvironment and deepen clinical responses. In addition, we continue to conduct translational assessments of treated patients to guide next generation TCR-T therapy approaches including potential combination and multiplexed TCR-T cell therapies.

Financial Overview

Collaboration Revenue

We recognize research and development funding revenue over the estimated period of performance. To date we have not generated product revenue. Unless and until we receive approval from the FDA and/or other regulatory authorities for our product candidates, we cannot sell our products and will not have product revenue.

Research and Development Expenses

Our research and development expenses consist primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities, reagents and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to contract research organizations in conjunction with clinical trials, fees paid to contract research organizations in conjunction with costs of materials used in research and development, consulting, license and milestone payments and sponsored research fees paid to third parties.

Our future research and development expenses in support of our current and future programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous preclinical studies for safety, toxicology and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products or indications. Completion of clinical trials may take several years or more, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product. It is not unusual for preclinical and clinical development of each of these types of products to require the expenditure of substantial resources.

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

- The number of clinical sites included in the trials;
- The length of time required to enroll suitable patients;
- The number of patients that ultimately participate in the trials;
- The length of time and cost to develop and optimize manufacturing processes;
- The cost to manufacture the clinical products for patients;
- The duration of patient follow-up to ensure the absence of long-term product-related adverse events; and
- The efficacy and safety profile of the product.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our product development strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation, consulting and professional fees, including patent related costs, general corporate costs and facility costs not otherwise included in research and development expenses or cost of product revenue.

Other Income (Expense)

Other income (expense) consists primarily of interest expense associated with our Amended Loan and Security Agreement, as defined below, and sublease income, which started accruing on July 1, 2022.

Results of Operations for the Fiscal Years ended December 31, 2022 and 2021

	Year Ended December 31,	
	2022	2021
Collaboration revenue	$ 2,922	$ 398
Operating expenses:		
Research and development	25,018	49,643
General and administrative	13,142	27,564
Gain on lease modification	(133)	—
Property and equipment and right-of-use assets impairment	—	740
Total operating expenses	38,027	77,947
Loss from operations	(35,105)	(77,549)
Other income (expense):		
Interest expense	(3,154)	(1,189)
Other income (expense), net	529	(13)
Other income (expense), net	(2,625)	(1,202)
Net loss	$ (37,730)	$ (78,751)

Collaboration Revenue

Collaboration revenue during the years ended December 31, 2022 and 2021 were as follows:

	Year Ended December 31,			
	2022	2021	Change	
($ in thousands)				
Collaboration revenue	$ 2,922	$ 398	$ 2,524	634%

Collaboration revenue during the year ended December 31, 2022 was $2.9 million compared to $0.4 during the year ended December 31, 2021. The increase was primarily due to $2.9 million we recognized under our license and collaboration agreement with Solasia Pharma K.K upon achievement of a milestone.

Research and Development Expenses

Research and development expenses during the years ended December 31, 2022 and 2021 were as follows:

	Year Ended December 31,			
	2022	2021	Change	
($ in thousands)				
Research and development expenses	$ 25,018	$ 49,643	$ (24,625)	(50)%

Research and development expenses for the year ended December 31, 2022 decreased by $24.6 million when compared to the year ended December 31, 2021 primarily due to a decrease in program-related costs of $9.7 million, mainly related to the winding down of our IL-12 and CAR-T programs, a $15.5 million decrease in employee-related expenses due to our reduced headcount, a $1.4 million decrease in consulting expenses due to our reduced use of outside service providers and a $0.5 million decrease in facilities and other expenses following the reduction of our real estate footprint in 2022. These decreases were partially offset by a one-time $2.5 million expense to MD Anderson under the terms of our License Agreement resulting from Solasia's achievement of a milestone.

Our strategic restructuring event during the year ended December 31, 2021 resulted in the termination of approximately 60 full-time employees, which led to the decrease in employee-related expenses. We currently do not anticipate similar events in the future.

General and Administrative Expenses

General and administrative expenses during the years ended December 31, 2022 and 2021 were as follows:

	Year Ended December 31,			
	2022	2021	Change	
($ in thousands)				
General and administrative expenses	$ 13,142	$ 27,564	$ (14,422)	(52)%

General and administrative expenses for the year ended December 31, 2022 decreased by $14.4 million as compared to the year ended December 31, 2021, primarily due to a $12.4 million decrease in employee-related expenses as a result of our reduced headcount, a $1.7

million decrease in consulting expenses due to lower legal costs and reduced use of consultants and a $0.3 million decrease in facilities and other expenses following the reduction of our real estate footprint in 2022.

Our strategic restructuring event during the year ended December 31, 2021 resulted in the termination of approximately 60 full-time employees, which led to the decrease in employee-related expenses. We currently do not anticipate similar events in the future.

Gain on lease modification

Gain on lease modifications during the years ended December 31, 2022 and 2021 was as follows:

	Year Ended December 31,			
	2022	2021	Change	
($ in thousands)				
Gain on lease modification	$ (133)	$ —	$ (133)	100%

Gain on lease modification during the year ended December 31, 2022 was $0.1 million as compared to $0 during the year ended December 31, 2021. As a result of a real estate lease modification during the second quarter of 2022, the associated lease liability and right-of-use asset were remeasured based on the revised lease payments, resulting in a gain of $0.1 million.

Impairments

Impairments during the years ended December 31, 2022 and 2021 were as follows:

	Year ended December 31,			
	2022	2021	Change	
($ in thousands)				
Property and equipment and right-of-use assets impairment	$ —	$ 740	$ (740)	100%

There were no impairments during the year ended December 31, 2022, compared to $0.7 during the year ended December 31, 2021. Due to a change in the intended use of our Boston office, an impairment charge of $0.6 million to the right-of-use asset and $0.1 million to leasehold improvements and other assets associated with the office was recognized during the year ended December 31, 2021.

Other Income (Expense)

Other income (expense) during the years ended December 31, 2022 and 2021 was as follows:

	Year Ended December 31,			
	2022	2021	Change	
($ in thousands)				
Interest expense	$ (3,154)	$ (1,189)	$ (1,965)	165%
Other income (expense), net	529	(13)	542	(4169)%
Total	$ (2,625)	$ (1,202)	$ (1,423)	118%

Total other income (expense), net for the year ended December 31, 2022 increased by $1.4 million as compared to the year ended December 31, 2021 due to additional interest expense associated with our Amended Loan and Security Agreement, as defined below, of $2.0 million, partially offset by increased interest income of $0.5 million recognized during the year ended December 31, 2022 as a result of higher interest rates earned on our cash balances.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any revenue from product sales. Since inception, we have incurred net losses and negative cash flows from our operations.

To date, we have financed our operations primarily through public offerings of our common stock, private placements of our convertible equity securities, term debt and collaborations. Through December 31, 2022, we have received an aggregate of $729.1 million from issuances of equity and $25.0 million from our Amended Loan and Security Agreement.

We follow the guidance of ASC Topic 205-40, *Presentation of Financial Statements - Going Concern*, in order to determine whether there is substantial doubt about our ability to continue as a going concern for one year after the date our financial statements are issued. Given our current development plans and cash management efforts, we anticipate that our cash resources will be sufficient to fund operations into the fourth quarter of 2023. Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in our focus and direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If adequate additional funds are not available when required, management may need to curtail its development efforts and planned operations to conserve cash.

Based on the current cash forecast, management has determined that our present capital resources will not be sufficient to fund our planned operations for at least one year from the issuance date of the financial statements, which raises substantial doubt as to our ability to continue as a going concern. This forecast of cash resources and planned operations is forward-looking information that involves risks and uncertainties, and the actual amount of expenses could vary materially and adversely as a result of a number of factors.

2022 Public Offering

On November 29, 2022, we entered into an underwriting agreement, or the Underwriting Agreement, with Cantor Fitzgerald & Co., or the Underwriter, as the sole underwriter, relating to the issuance and sale in an underwritten offering, or the Offering, of 24,228,719 shares of our common stock, or the Firm Shares, to the Underwriter at a price of $0.6191 per share.

Our net proceeds from the Offering were $14.7 million (before accounting for the partial exercise of the Underwriter's option as described below) after deducting underwriting discounts and commissions and offering expenses payable by us.

Under the terms of the Underwriting Agreement, we granted the Underwriter an option, exercisable for 30 days, to purchase up to an additional 3,634,307 shares of common stock, or, together with the Firm Shares, the Shares, at the same price per share as the Firm Shares. On January 5, 2023, the Underwriter partially exercised its option to purchase 216,294 shares of common stock.

All of the Shares sold in the Offering were sold by us.

2022 Equity Distribution Agreement

On August 12, 2022, we entered into an Equity Distribution Agreement, or the Equity Distribution Agreement, with Piper Sandler & Co., or Piper Sandler, pursuant to which we can offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50 million through Piper Sandler as our sales agent in an “at the market offering.” Piper Sandler will receive a commission of 3.0% of the gross proceeds of any common stock sold under the Equity Distribution Agreement. During the year ended December 31, 2022, there were no sales of our common stock under the Equity Distribution Agreement. In connection with entering into the Equity Distribution Agreement, we concurrently terminated, effective August 12, 2022, the Open Market Sale Agreement, dated June 21, 2019, governing our former “at the market offering” program.

2021 Loan and Security Agreement

On August 6, 2021, we entered into the Loan and Security Agreement. The Loan and Security Agreement provided for an initial term loan of $25.0 million funded at the closing, with an additional tranche of $25.0 million available if certain funding and clinical milestones were met by August 31, 2022. Effective December 28, 2021, we entered into the Amended Loan and Security Agreement, or the Amended Loan and Security Agreement.

Under the terms of the Amended Loan and Security Agreement, the SVB Facility was modified to eliminate the additional tranche, which remained unfunded, leaving only the initial $25.0 million as the full amount available under the SVB Facility. The SVB Facility bears interest at a floating rate per annum on the outstanding loans, payable monthly, at the greater of (a) 7.75% and (b) the current published U.S. prime rate, plus a margin of 4.5%. The Amended Loan and Security Agreement provided for an interest-only period through August 31, 2022. Commencing on September 1, 2022, aggregate outstanding borrowings became repayable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding obligations under the Amended Loan and Security Agreement are due and payable on August 1, 2023. We will also owe SVB 5.75% of the original principal amounts borrowed as a final payment. We are permitted to make up to two prepayments, subject to a prepayment premium of the amount being prepaid, ranging from 1.00% to 2.00%, of the SVB Facility, each such prepayment to be at least $5.0 million plus all accrued and unpaid interest on the portion being prepaid.

As a result of not achieving certain milestones specified in the Amended Loan and Security Agreement on or prior to August 31, 2022, we were required to cash collateralize half of the sum of the then-outstanding principal amount of the SVB Facility, plus an amount equal to 5.75% of the original principal amount of the SVB Facility. As of December 31, 2022, we have collateralized $13.9 million, which is classified as restricted cash on our Balance Sheet. So long as no event of default has occurred and subject to certain other terms related to the remaining

outstanding balance under the SVB Facility being satisfied, $2.5 million will be released from the collateral account following the eighth scheduled payment of principal and interest, and a further $4.0 million will be released following the tenth scheduled payment of principal and interest. The SVB Facility and related obligations under the Amended Loan and Security Agreement are secured by substantially all of our properties, rights and assets, except for its intellectual property (which is subject to a negative pledge under the Amended Loan and Security Agreement). In addition, the Amended Loan and Security Agreement contains customary representations, warranties, events of default and covenants.

In connection with our entry into the Loan and Security Agreement, we issued to SVB warrants to purchase (i) up to 432,844 shares of our common stock, in the aggregate, and (ii) up to an additional 432,842 shares of Common Stock, in the aggregate, in the event we achieved certain clinical milestones, in each case at an exercise price per share of $2.22. In connection with our entry into the Amended Loan and Security Agreement, we amended and restated the warrants issued to SVB. As amended and restated, the warrants are for up to 649,615 shares of our common stock, in the aggregate, at an exercise price per share of $1.16, or the SVB Warrants. The SVB Warrants expire on August 6, 2031.

Cash Flows

The following table summarizes our net increase (decrease) in cash and cash equivalents for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
($ in thousands)	**2022**	**2021**
Net cash provided by (used in):		
Operating activities	$ (29,232)	$ (61,468)
Investing activities	(193)	(3,323)
Financing activities	6,367	25,776
Net decrease in cash and cash equivalents	$ (23,058)	$ (39,015)

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating cash flow is derived by adjusting our net loss for:

- Non-cash operating items such as depreciation and stock-based compensation; and
- Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations.

Net cash used in operating activities for the year ended December 31, 2022 was $29.2 million, as compared to $61.5 million for the year ended December 31, 2021. The decrease was primarily related to the reduction of our net loss by $41.1 million, partially offset by the extent of non-cash adjustments and working capital impacts.

The net cash used in operating activities for the year ended December 31, 2022 was primarily a result of our net loss of $37.7 million, adjusted for $9.6 million of non-cash items such as depreciation, stock-based compensation and a decrease in the carrying amount of right-of-use assets, a decrease in accounts receivable of $1.1 million and a decrease in prepaid expenses and other assets of $1.0 million, offset by a decrease in accrued expenses of $0.7 million and a decrease in lease liabilities of $2.5 million. The net cash used in operating activities for the year ended December 31, 2021 was primarily a result of our net loss of $78.8 million, adjusted for $14.5 million of non-cash items such as depreciation and stock-based compensation and a decrease in accrued expenses of $10.5 million, offset by a decrease in receivables of $3.6 million, a decrease in prepaid expenses and other assets of $9.4 million and an increase in accounts payable of $0.3 million.

Net cash used in investing activities was $0.2 million for the year ended December 31, 2022 as compared to $3.3 million for the year ended December 31, 2021. The decrease in net cash used in investing activities for the year ended December 31, 2022 compared to the year ended December 31, 2021 was primarily a result of the decision to use available cash to expand our internal cell therapy capabilities in our Houston, Texas facilities during the first half of 2021.

Net cash provided by financing activities was $6.4 million for the year ended December 31, 2022 compared to $25.8 million for the year ended December 31, 2021. The $6.4 million provided by financing activities during the year ended December 31, 2022 related primarily to $14.7 million in net proceeds from the issuance of common stock (before accounting for the partial exercise of the Underwriter's option), offset by $8.3 million of repayments of long-term debt. Net cash provided by financing activities was $25.8 million for the year ended December 31, 2021, related primarily to proceeds from our $25.0 million SVB Facility and the proceeds from the exercise of stock options equal to $1.0 million.

Operating Capital and Capital Expenditure Requirements

We anticipate that losses will continue for the foreseeable future. As of December 31, 2022, our accumulated deficit was approximately $880.6 million. Our actual cash requirements may vary materially from those planned because of a number of factors, including:

- changes in the focus, direction and pace of our development programs;
- the effect of competing technologies and market developments;
- the scope, progress, timing, costs and results of our TCR-T Library Phase 1/2 Trial for the treatment of certain solid tumors and costs associated with the development of our product candidates;
- our headcount growth as we rebuild our workforce with a focus on our TCR program and scale our manufacturing capabilities;
- our ability to secure partnering arrangements; and
- costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights, or other developments.

As of December 31, 2022, we had approximately $53.0 million of cash, cash equivalents and restricted cash. Our restricted cash of $13.9 million relates to the Amended Loan and Security Agreement. Given our current development plans, we anticipate our cash resources will be sufficient to fund our operations into the fourth quarter of 2023. In order to continue our operations beyond our forecasted runway we will need to raise additional capital, and we have no committed sources of additional capital at this time. The forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of our expenses could vary materially and adversely as a result of a number of factors. We have based our estimates on assumptions that may prove to be wrong, and our expenses could prove to be significantly higher than we currently anticipate. Management does not know whether additional financing will be on terms favorable or acceptable to us when needed, if at all. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our product candidates, management may need to curtail its development efforts and planned operations.

Working capital, which excludes restricted cash, as of December 31, 2022 was $15.7 million, consisting of $39.9 million in current assets and $24.2 million in current liabilities. Working capital as of December 31, 2021 was $62.8 million, consisting of $78.8 million in current assets and $16.0 million in current liabilities.

Operating Leases

Our commitments for operating leases relate to laboratory and office space in Houston, Texas and office space in Boston, Massachusetts. On December 21, 2015 and April 15, 2016, we renewed the sublease for our office space in Boston through August 31, 2021. On April 22, 2021, we extended our sublease for a portion of office space at our office in Boston through August 31, 2026.

On March 12, 2019, we entered into a lease agreement for office space in Houston at MD Anderson through April 2021. On October 15, 2019, we entered into another lease agreement for additional office and laboratory space in Houston through February 2027. On April 7, 2020, we entered into amendments to our existing lease to lease additional office and laboratory space in Houston through February 2027. In June and September 2020, we entered into short-term leases in Houston for additional office and laboratory space. On December 15, 2020, we entered into a second lease in Houston with MD Anderson which provided us additional office and laboratory space through April 2028.

In April 2022, we modified our real estate lease agreement executed on December 15, 2020 with MD Anderson. The modification reduced our leased space from 18,111 square feet to 3,228 square feet. As a result, the associated lease liability and right-of-use asset were remeasured to $0.4 million based on revised lease payments.

In June 2022, we executed an agreement to sub-sublease 4,772 square feet of our subleased office space in Boston. The term of the sub-sublease is from July 1, 2022 to June 30, 2025 and provides the sub-subtenant with an option to extend through to July 31, 2026. For the year ended December 31, 2022, we recognized $0.1 million in lease income, which is classified within other income (expense), net in the Statement of Operations.

Royalty and License Fees

On May 28, 2019, we entered into the Patent License with the NCI. The terms of the Patent License require us to pay the NCI minimum annual royalties in the amount of $0.3 million, which will be reduced to $0.1 million once the aggregate minimum annual royalties paid by us equals $1.5 million. For the year ended December 31, 2022, we recognized $0.3 million in royalty payments under the Patent License, and we recognized $0.3 million in royalty payments for the year ended December 31, 2021. As of December 31, 2022, we have paid a total of $0.5 million in minimum annual royalty payments under the Patent License.

Pursuant to the Patent License, we are also required to make performance-based payments contingent upon the successful completion of clinical and regulatory benchmarks relating to the licensed products. Of such payments, the aggregate potential benchmark payments are $4.3 million, of which aggregate payments of $3.0 million are due only after marketing approval in the United States or in Europe, Japan, Australia, China or India. The first benchmark payment of $0.1 million was due upon the initiation of our TCR-T Library Phase 1/2 Trial. In addition, we are required to pay the NCI one-time benchmark payments following aggregate net sales of licensed products at certain aggregate net sales ranging from $250.0 million to $1.0 billion. The aggregate potential amount of these benchmark payments is $12.0 million. Payments of $0.1 million were made during the year ended December 31, 2022, and no payments were made during the year ended December 31, 2021.

On October 5, 2018, we entered into the License Agreement with PGEN. Under the License Agreement, we are obligated to pay PGEN an annual licensing fee of $0.1 million expected to be paid through the term of the agreement and we have also agreed to reimburse certain historical costs of PGEN up to $1.0 million. For the years ended December 31, 2022 and 2021, we have made licensing fee payments in accordance with the terms of the agreement.

Pursuant to the terms of the License Agreement, we are responsible for contingent milestone payments totaling up to an additional $52.5 million for each exclusively licensed program upon the initiation of later stage clinical trials and upon the approval of exclusively licensed products in various jurisdictions. In addition, we will pay PGEN tiered royalties ranging from low-single digit to high-single digit on the net sales derived from the sales of any approved IL-12 products and CAR products. We will also pay PGEN royalties ranging from low-single digit to mid-single digit on the net sales derived from the sales of any approved TCR products, up to a maximum royalty amount of $100.0 million in the aggregate. We will also pay PGEN 20% of any sublicensing income received by us relating to the licensed products. We are responsible for all development costs associated with each of the licensed products. PGEN will pay us royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of PGEN's CAR products, up to a maximum royalty amount of $100.0 million.

In June 2022, Solasia announced that darinaparsin had been approved from relapsed or refractory Peripheral T-Cell Lymphoma by the Ministry of Health, Labor and Welfare in Japan. During the year ended December 31, 2022, the Company recorded $2.9 million of collaboration revenue under the Solasia License and Collaboration Agreement primarily related to Solasia's achievement of certain sales-based milestones in Japan, compared to $0.4 million during the year ended December 31, 2021.

Critical Accounting Policies and Significant Estimates

Our Management's Discussion and Analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following are our more significant estimates and judgments used in the preparation of our financial statements:

- Clinical trial expenses and other research and development expenses;
- Collaboration agreements;
- Fair value measurements of stock-based compensation; and
- Income taxes.

Research and Development Costs / Clinical Trial Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a predetermined schedule or when contractual milestones are met; however, a few require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research services on our behalf and clinical trials;
- investigative sites or other providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing, development, and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in changes to our previous

estimates, which we considered reasonably reliable at the time. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Revenue Recognition from Collaboration Agreements

We primarily generate revenue through collaboration arrangements with strategic partners for the development and commercialization of product candidates. Commencing January 1, 2018, we recognized revenue in accordance with Financial Accounting Standards Board ("FASB") ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), which replaced ASC 605, *Multiple Element Arrangements*, as used in historical years. The core principle of ASC 606 is that an entity should recognize revenue to depict the transfer of promised goods and/or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and/or services. To determine the appropriate amount of revenue to be recognized for arrangements that we determine are within the scope of ASC 606, we perform the following steps: (i) identify the contract(s) with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when (or as) each performance obligation is satisfied.

We recognize collaboration revenue under certain of our license or collaboration agreements that are within the scope of ASC 606. Our contracts with customers typically include promises related to licenses to intellectual property, research and development services and options to purchase additional goods and/or services. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Contracts that include an option to acquire additional goods and/or services are evaluated to determine if such option provides a material right to the customer that it would not have received without entering into the contract. If so, the option is accounted for as a separate performance obligation. If not, the option is considered a marketing offer which would be accounted for as a separate contract upon the customer's election.

The terms of our arrangements with customers typically include the payment of one or more of the following: (i) non-refundable, up-front payment, (ii) development, regulatory and commercial milestone payments, (iii) future options and (iv) royalties on net sales of licensed products. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. We measure the transaction price based on the amount of consideration to which we expect to be entitled in exchange for transferring the promised goods and/or services to the customer. We utilize the most likely amount method to estimate the amount of variable consideration, to predict the amount of consideration to which we will be entitled. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, we evaluate whether the associated event is considered probable of achievement and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the control of us or the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, we reevaluate the probability of achievement of each milestone and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, we recognize revenue upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

We allocate the transaction price to each performance obligation identified in the contract on a relative standalone selling price basis. However, certain components of variable consideration are allocated specifically to one or more particular performance obligations in a contract to the extent both of the following criteria are met: (i) the terms of the payment relate specifically to the efforts to satisfy the performance obligation or transfer the distinct good or service and (ii) allocating the variable amount of consideration entirely to the performance obligation or the distinct good or service is consistent with the allocation objective of the standard whereby the amount allocated depicts the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services. We develop assumptions that require the use of judgment to determine the standalone selling price for each performance obligation identified in each contract. The key assumptions utilized in determining the standalone selling price for each performance obligation may include forecasted revenue, development timelines, estimated research and development costs, discount rates, likelihood of exercise and probabilities of technical and regulatory success.

Revenue is recognized based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good and/or service to the customer. For performance obligations that are satisfied over time, we recognize revenue by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress which depicts the performance in transferring control of the associated goods and/or services to the customer. We use input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. We evaluate the

measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

Accounting for Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period. Stock-based compensation expense is based on the number of awards ultimately expected to vest and is reduced for forfeitures as they occur. Consistent with prior years, the Company uses the Black-Scholes option pricing model, which requires estimates of the expected term option holders will retain their options before exercising them and the estimated volatility of the Company's common stock price over the expected term.

We review our valuation assumptions periodically and, as a result, we may change our valuation assumptions used to value share-based awards granted in future periods. Such changes may lead to a significant change in the expense we recognize in connection with share-based payments.

Our assumptions are estimated as follows:

- the fair market value of our common stock is considered the quoted market price on Nasdaq;
- the expected volatility is based on the historical stock volatility of our common stock over a sufficient period of time equal to the expected term of the option;
- the expected term represents the period that our stock options are expected to be outstanding;
- the risk-free interest rate is based on the yields of U.S. Treasury securities with maturities commensurate with the expected term of the award; and
- we have not paid dividends on our common stock nor do we expect to pay dividends in the foreseeable future.

Income Taxes

In preparing our financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which, prior to the consideration for the need for a valuation allowance, are included on our Balance Sheet. Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income and the effects of tax planning strategies. Our estimates of future taxable income include, among other items, our estimates of future income tax deductions related to the exercise of stock options. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to establish a valuation allowance, which could materially impact our financial position and results of operations.

We account for uncertain tax positions using a "more-likely-than-not" threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate uncertain tax positions on an annual basis and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the "more-likely-than-not" threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews; we have no plans to appeal or litigate any aspect of the tax position; and we believe that it is highly unlikely that the taxing authority would examine or re-examine the related tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

Recent Accounting Pronouncements

For a discussion of new accounting standards, please read Note 3 to the accompanying financial statements, *Summary of Significant Accounting Principles* included in this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, we are not required to provide the information under this Item 7A.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-26 of this Annual Report and is incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer and our principal accounting officer, we have evaluated the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) or 15d-15(e) promulgated under the Exchange Act, as of December 31, 2022. Based on that evaluation, our principal executive officer and principal financial officer has concluded that as of December 31, 2022, our disclosure controls and procedures were effective as described below under "*Management's Report on Internal Control over Financial Reporting*."

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13(a)-15(f) and 15(d)-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and our principal accounting officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer and our principal accounting officer, we assessed our internal control over financial reporting as of December 31, 2022, based on criteria for effective internal control over financial reporting established in Internal Control - Integrated Framework (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our management's assessment of the effectiveness of our internal control over financial reporting included testing and evaluating the design and operating effectiveness of our internal controls. In management's opinion, we have maintained effective internal control over financial reporting as of December 31, 2022, based on the criteria discussed above.

Inherent Limitations on Internal Controls

Our management, including our principal executive officer and principal financial officer, and our principal accounting officer, do not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13(a)-15(f) of the Exchange Act) that occurred during the fiscal year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(1) Financial Statements:

The Financial Statements required to be filed by Item 8 of this Annual Report, and filed in this Item 15, are as follows:

(2) Financial Statement Schedules:

Schedules are omitted because they are not applicable, or are not required, or because the information is included in the financial statements and notes thereto.

(3) Exhibits:

Exhibit No.	Description of Document
2.1	Agreement and Plan of Merger among the Registrant (formerly "EasyWeb, Inc."), ZIO Acquisition Corp. and ZIOPHARM, Inc., dated August 3, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K, SEC File No. 000-32353, filed August 9, 2005).
3.1	Amended and Restated Certificate of Incorporation, and all amendments thereto (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
3.2	Certificate of Merger dated September 13, 2005, relating to the merger of ZIO Acquisition Corp. with and into ZIOPHARM, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K, SEC File No. 000-32353, filed September 19, 2005).
3.3	Certificate of Ownership of the Registrant (formerly "EasyWeb, Inc.") dated as of September 14, 2005, relating the merger of ZIOPHARM, Inc. with and into the Registrant, and changing the Registrant's corporate name from EasyWeb, Inc. to ZIOPHARM Oncology, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K, SEC File No. 000-32353, filed September 19, 2005).
3.4	Amended and Restated Certificate of Designation, Preferences and Rights of Series 1 Preferred Stock, as filed with the Delaware Secretary of State on July 1, 2016 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K/A, SEC File No. 001-33038, filed July 1, 2016).
3.5	Amended and Restated Bylaws of the Registrant, dated as of September 21, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed September 22, 2020).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).
4.2	Form of Option for the Purchase of Shares of common stock dated August 30, 2004 and issued to The University of Texas M. D. Anderson Cancer Center (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-KSB, SEC File No. 000-32353, filed March 20, 2006).
4.3	Schedule identifying Material Terms of Options for the Purchase of Shares of Common Stock (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-KSB, SEC File No. 000-32353, filed March 20, 2006).
4.4	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed November 13, 2018).
4.5#	Warrant to Purchase Common Stock issued to The University of Texas M. D. Anderson Cancer Center (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 2, 2020).
4.6	Form of Warrant to Purchase Shares of Common Stock issued to SVB and certain of its Affiliates, dated December 28, 2021 (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
4.7	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.3+	ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed September 24, 2018).

10.4+	Form of Restricted Stock Agreement Granted Under the ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed June 26, 2012).
10.5+	Form of Option Agreement Granted Under the ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed June 26, 2012).
10.7+	Form of Inducement Award Grant Notice and Inducement Award Grant Agreement (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8, SEC File No. 333-238090, filed May 8, 2020).
10.8+	ZIOPHARM Oncology, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed July 1, 2020).
10.9+	Form of Restricted Stock Agreement Granted Under the ZIOPHARM Oncology, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.10+	Form of Stock Option Agreement Granted Under the ZIOPHARM Oncology, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.11+	Form of Indemnity Agreement for directors and executive officers (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed January 31, 2013).
10.16+	Employment Agreement, dated August 24, 2021, by and between the Registrant and Kevin S. Boyle Sr. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed August 30, 2021).
10.23#	Form of Retention Bonus Agreement (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.24#	License Agreement by and among the Registrant, Intrexon Corporation and The University of Texas System Board of Regents on behalf of The University of Texas M.D. Anderson Cancer Center dated as of January 13, 2015 (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed January 28, 2015).
10.25†	Exclusive License Agreement by and between the Registrant, Precigen, Inc. and Intrexon Corporation, dated October 5, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed November 9, 2018).
10.26#	Amendment No. 1 to the Exclusive License Agreement by and between the Registrant and PGEN Therapeutics, Inc. (formerly known as Precigen, Inc.), dated October 15, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q SEC File No. 001-33038, filed November 5, 2020).
10.27†	License and Collaboration Agreement by and among the Registrant, Intrexon Corporation and Ares Trading S.A. dated as of March 27, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed April 2, 2015).
10.28#	Research and Development Agreement by and among the Registrant, Intrexon Corporation and The University of Texas M.D. Anderson Cancer Center dated as of August 17, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed August 21, 2015).
10.29	First Amendment to the Research and Development Agreement by and among the Registrant, Intrexon Corporation and The University of Texas M.D. Anderson Cancer Center dated as of August 30, 2016 (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 5, 2019).
10.30	Second Amendment to the Research and Development Agreement by and among the Registrant, Intrexon Corporation and The University of Texas M.D. Anderson Cancer Center dated as of January 17, 2017 (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 5, 2019).
10.31	Third Amendment to the Research and Development Agreement by and among the Registrant, Intrexon Corporation and The University of Texas M.D. Anderson Cancer Center dated as of November 14, 2017 (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 5, 2019).
10.32	Fourth Amendment to Research and Development Agreement, dated September 19, 2019 by and among the Registrant, The University of Texas MD Anderson Cancer Center and Precigen, Inc. (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed November 7, 2019).
10.33#	Fifth Amendment to Research and Development Agreement, dated October 22, 2019 by and among the Registrant and The University of Texas MD Anderson Cancer Center (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 2, 2020).
10.34#	2019 Research and Development Agreement, dated October 22, 2019, by and between the Registrant and The University of Texas MD Anderson Cancer Center (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 2, 2020).
10.35#	Patent License Agreement, dated as of May 28, 2019, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed August 8, 2019).
10.36#	First Amendment to Patent License Agreement, dated as of January 8, 2020, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 2, 2020).

10.37#	Second Amendment to Patent License Agreement, dated as of September 28, 2020, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 000-33038, filed November 5, 2020).
10.38#	Third Amendment to Patent License Agreement, dated as of April 16, 2021, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.39#	Fourth Amendment to Patent License Agreement, dated as of May 4, 2021, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.40#	Fifth Amendment to Patent License Agreement, dated as of August 13, 2021, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.40 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.41#	Cooperative Research and Development Agreement, dated January 9, 2017, by and among the Registrant, the National Cancer Institute, and Intrexon Corporation (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038, filed September 26, 2019).
10.42	First Amendment to the Cooperative Research and Development Agreement, dated March 23, 2018, by and among the Registrant, National Cancer Institute, Intrexon Corporation and Precigen, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038, filed September 26, 2019).
10.43#	Second Amendment to the Cooperative Research and Development Agreement, dated February 1, 2019, by and among the National Cancer Institute, the Registrant and Precigen, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038, filed September 26, 2019).
10.44	Third Amendment to the Cooperative Research and Development Agreement, dated March 15, 2022, by and among the National Cancer Institute and the Registrant (incorporated by reference to Exhibit 10.44 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.45	Fourth Amendment to the Cooperative Research and Development Agreement, dated June 24, 2022, by and between the National Cancer Institute and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed August 15, 2022).
10.46	Lease Agreement, dated as of October 15, 2019, by and between the Registrant and The University of Texas System Board of Regents on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.47	First Amendment, dated as of April 7, 2020, to the Lease Agreement, dated as of October 15, 2019, by and between the Registrant and The University of Texas System Board of Regents on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.40 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.48	Second Amendment, dated as of April 7, 2020, to the Lease Agreement, dated as of October 15, 2019, by and between the Registrant and The University of Texas System Board of Regents on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.41 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.49	Third Amendment, dated as of December 15, 2020, to the Lease Agreement, dated as of October 15, 2019, by and between the Registrant and The University of Texas System Board of Regents on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.42 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.50	Lease Agreement dated as of December 15, 2020, by and between the Registrant and The University of Texas System Board of Regents on behalf of The University of Texas M.D. Anderson Cancer Center (incorporated by reference to Exhibit 10.43 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.51	Agreement dated February 4, 2021, by and among the Registrant, WaterMill Asset Management Corp. and Robert W. Postma (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed February 5, 2021).
10.52	Loan and Security Agreement by and among the Registrant, the lenders party thereto and Silicon Valley Bank, as administrative agent and collateral agent, dated August 6, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed November 8, 2021).
10.53	First Amendment to the Loan and Security Agreement by and among the Registrant, the lenders party thereto and Silicon Valley Bank, as administrative agent and collateral agent, dated December 28, 2021 (incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.54	Equity Distribution Agreement, dated August 12, 2022, by and between Piper Sandler & Co. and the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed August 15, 2022).

10.55	Underwriting Agreement, dated as of November 29, 2022, by and between Cantor Fitzgerald & Co. and the Registrant (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed November 30, 2022).
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (incorporated by reference to the signature page of this Annual Report on Form 10-K).
31.1*	Certification of Principal Executive Officer pursuant to Exchange Act Rule 13a-14(a) or 15(d)-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File-the cover page interactive data is embedded within the Inline XBRL document or included within the Exhibit 101 attachments
*	Filed herewith.
**	Furnished herewith.
+	Indicates management contract or compensatory plan.
†	Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions of this document.
#	Portions of this document (indicated by "[***]") have been omitted because such information is not material and is the type of information that the Registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALAUNOS THERAPEUTICS, INC.

Date: March 7, 2023

By: /s/ Kevin S. Boyle, Sr.
Kevin S. Boyle, Sr.
Chief Executive Officer and Director
(Principal Executive Officer and Principal Financial Officer)

Date: March 7, 2023

By: /s/ Michael Wong
Michael Wong
Vice President, Finance
(Principal Accounting Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kevin S. Boyle, Sr. and Michael Wong, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Kevin S. Boyle, Sr. Kevin S. Boyle, Sr.	Chief Executive Officer and Director *(Principal Executive Officer and Principal Financial Officer)*	March 7, 2023
/s/ Michael Wong Michael Wong	Vice President, Finance *(Principal Accounting Officer)*	March 7, 2023
/s/ Christopher Bowden Christopher Bowden	Director	March 7, 2023
/s/ James Huang James Huang	Director	March 7, 2023
/s/ Robert W. Postma Robert W. Postma	Director	March 7, 2023
/s/ Mary Thistle Mary Thistle	Director	March 7, 2023
/s/ Jaime Vieser Jaime Vieser	Director	March 7, 2023
/s/ Holger Weis Holger Weis	Director	March 7, 2023

Alaunos Therapeutics, Inc.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Alaunos Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Alaunos Therapeutics, Inc. and its subsidiaries (the Company) as of December 31, 2022 and 2021, the related statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes to the financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The Company's Ability to Continue as a Going Concern

The accompanying 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 recurring operating losses since its inception and will be required to raise additional capital to fund operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The 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 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accruals for Clinical Trials and Other Research and Development Expenses

As discussed in Note 3 to the financial statements, the Company accrues costs for clinical trials and other research and development expenses based on estimates of costs incurred through the balance sheet date that have not been invoiced by the clinical research organizations, clinical study sites, consultants, or other vendors. This process involves reviewing open contracts and purchase orders, communicating with vendors and internal personnel to identify services that have been performed, and estimating the level of service performed and the associated costs incurred for the services when the Company has not yet been invoiced or otherwise notified of the actual costs. The Company's accrual for clinical trial and preclinical study expenses totaled $2.4 million at December 31, 2022 as disclosed in Note 6.

We identified the accruals for clinical trials and other research and development expenses to be a critical audit matter because auditing the Company's accruals is complex as the information necessary to make an estimate is accumulated from multiple sources and there may be delays in invoicing from clinical study sites and other vendors, or payments may depend on factors such as the completion of clinical trial milestones. Additionally, in certain circumstances, it requires judgment, as the timing and pattern of vendor invoicing may not correspond to the level of services provided.

How We Addressed the Matter in our Audit

Our audit procedures to test the accruals for clinical trial and preclinical studies expenses included, among others:

- We tested the accuracy and completeness of the underlying data used in the estimates and evaluated the reasonableness of assumptions used by management.
- We inspected certain contracts with third parties and related information received by the Company to test proper recording of costs incurred to date.

- We corroborated the progress of research and development activities through discussion with the Company's research and development personnel, specifically those who oversee the projects, and confirmations with the third parties.
- We performed analytical procedures over fluctuations in accruals on a department level throughout the year.
- We tested subsequent invoices received from third parties and cash disbursements to assess completeness of recorded accruals.

/s/ RSM US LLP

We have served as the Company's auditor since 2010.

Boston, Massachusetts
March 7, 2023

Alaunos Therapeutics, Inc.

BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 39,058	$ 76,054
Restricted cash	13,938	—
Receivables	4	1,111
Prepaid expenses and other current assets	799	1,666
Total current assets	53,799	78,831
Property and equipment, net	8,460	10,941
Right-of-use asset	2,136	4,420
Deposits	42	42
Other non-current assets	500	631
Total assets	$ 64,937	$ 94,865
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,389	$ 1,368
Long-term debt, current	16,765	7,868
Accrued expenses	5,454	6,076
Lease liability, current	558	729
Total current liabilities	24,166	16,041
Long-term debt	—	16,250
Lease liability, non-current	2,188	4,518
Other non-current liabilities	28	—
Total liabilities	$ 26,382	$ 36,809
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock $0.001 par value; 420,000,000 shares authorized, 240,410,761 shares issued and outstanding at December 31, 2022 and 350,000,000 shares authorized, 216,127,443 shares issued and outstanding at December 31, 2021	240	216
Additional paid-in capital	918,942	900,693
Accumulated deficit	(880,627)	(842,852)
Total stockholders' equity	38,555	58,057
Total liabilities and stockholders' equity	$ 64,937	$ 94,865

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

Alaunos Therapeutics, Inc.

STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

	For the Year Ended December 31,	
	2022	2021
Collaboration revenue	$ 2,922	$ 398
Operating expenses:		
Research and development	25,018	49,643
General and administrative	13,142	27,564
Gain on lease modification	(133)	—
Property and equipment and right-of-use assets impairment	—	740
Total operating expenses	38,027	77,947
Loss from operations	(35,105)	(77,549)
Other income (expense):		
Interest expense	(3,154)	(1,189)
Other income (expense), net	529	(13)
Other income (expense), net	(2,625)	(1,202)
Net loss	$ (37,730)	$ (78,751)
Basic and diluted net loss per share	$ (0.17)	$ (0.37)
Weighted average common shares outstanding, basic and diluted	217,130,311	214,399,074

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

Alaunos Therapeutics, Inc.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(in thousands, except share and per share data)

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	214,591,906	$ 215	$ 887,868	$ (764,101)	$ 123,982
Stock-based compensation	—	—	10,774	—	10,774
Exercise of employee stock options	363,109	—	1,036	—	1,036
Common stock issuance	5,991	—	—	—	—
Restricted stock awards	1,601,224	1	(1)	—	—
Cancelled restricted common stock	(434,787)	—	—	—	—
Issuance of warrants	—	—	1,016	—	1,016
Net loss	—	—	—	(78,751)	(78,751)
Balance at December 31, 2021	216,127,443	$ 216	$ 900,693	$ (842,852)	$ 58,057
Stock-based compensation	—	—	3,528	—	3,528
Restricted stock awards	280,000	—	—	—	—
Cancelled restricted common stock	(232,901)	—	—	—	—
Exercise of employee stock options	26,250	—	21	—	21
Repurchase of common stock	(18,750)	—	—	(45)	(45)
Issuance of common stock, net of expenses	24,228,719	24	14,700	—	14,724
Net loss	—	—	—	(37,730)	(37,730)
Balance at December 31, 2022	240,410,761	$ 240	$ 918,942	$ (880,627)	$ 38,555

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

Alaunos Therapeutics, Inc.

STATEMENTS OF CASH FLOWS

(in thousands)

	For the Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (37,730)	$ (78,751)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,759	2,597
Property and equipment and right-of-use asset impairment	—	740
Amortization of financing costs	981	383
Stock-based compensation	3,528	10,774
Decrease (increase) in the carrying amount of right-of-use assets	2,417	(352)
Gain on lease modification	(133)	—
Loss on sale of equipment	7	—
(Increase) decrease in:		
Receivables	1,107	3,555
Prepaid expenses and other current assets	867	9,189
Other non-current assets	131	201
Increase (decrease) in:		
Accounts payable	(25)	274
Accrued expenses	(668)	(10,512)
Lease liabilities	(2,501)	434
Other non-current liabilities	28	—
Net cash used in operating activities	(29,232)	(61,468)
Cash flows from investing activities:		
Purchases of property and equipment	(216)	(3,323)
Proceeds from the sale of property and equipment	23	—
Net cash used in investing activities	(193)	(3,323)
Cash flows from financing activities:		
Proceeds from long-term debt borrowing	—	25,000
Debt issuance costs	—	(260)
Proceeds from the exercise of stock options	21	1,036
Proceeds from the issuance of common stock	14,724	—
Repurchase of common stock	(45)	—
Repayment of long-term debt	(8,333)	—
Net cash provided by financing activities	6,367	25,776
Net decrease in cash, cash equivalents and restricted cash	(23,058)	(39,015)
Cash, cash equivalents and restricted cash, beginning of period	76,054	115,069
Cash, cash equivalents and restricted cash, end of period	$ 52,996	$ 76,054
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ 2,171	$ 630
Amounts included in accrued expenses and accounts payable related to property and equipment	$ 91	$ 134

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

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

1. Organization

Alaunos Therapeutics, Inc., which is referred to herein as "Alaunos," or the "Company," is a clinical-stage oncology-focused cell therapy company developing adoptive TCR therapies, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. On January 25, 2022, the Company changed its corporate name from ZIOPHARM Oncology, Inc. to Alaunos Therapeutics, Inc. The Company is leveraging its proprietary, non-viral *Sleeping Beauty* gene transfer platform and its novel cancer mutation hotspot TCR library to design and manufacture personalized cell therapies that target neoantigens arising from common tumor-related mutations in key oncogenic genes, including *KRAS, TP53* and *EGFR.*

The Company's operations to date have consisted primarily of conducting research and development and raising capital to fund those efforts. In May 2021, the Company announced that it will be winding down its existing Controlled IL-12 clinical program for the treatment of recurrent glioblastoma multiforme. The Company continues to seek a partner for this program.

The Company's amended and restated certificate of incorporation authorizes it to issue 420,000,000 shares of common stock. As of December 31, 2022, there were 240,410,761 shares of common stock outstanding and an additional 33,330,964 shares of common stock reserved for issuance pursuant to outstanding stock options and warrants.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company follows the guidance of Accounting Standards Codification, or ASC, Topic 205-40, *Presentation of Financial Statements - Going Concern*, in order to determine whether there is substantial doubt about its ability to continue as a going concern for one year after the date its financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates the substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (i) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued and (ii) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

The Company has operated at a loss since its inception in 2003 and has no recurring revenue from operations. The Company anticipates that losses will continue for the foreseeable future. As of December 31, 2022, the Company had approximately $53.0 million of cash, cash equivalents and restricted cash. The restricted cash of $13.9 million at December 31, 2022 is related to the Company's debt agreement (refer to Note 4, *Debt*). The Company's accumulated deficit at December 31, 2022 was approximately $880.6 million. Given its current development plans and cash management efforts, the Company anticipates cash resources will be sufficient to fund operations into the fourth quarter of 2023. The Company's ability to continue operations after its current cash resources are exhausted depends on future events, including its ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given, nor are within the Company's control. If adequate additional funds are not available when required, or if the Company is unsuccessful in entering into partnership agreements for further development of its product candidates, management may need to curtail its development efforts and planned operations to conserve cash until sufficient additional capital is raised. There can be no assurances that such a plan would be successful.

Based on the current cash forecast and the Company's dependence on its ability to obtain additional financing to fund its operations after the current resources are exhausted, about which there can be no certainty, management has determined that the Company's present capital resources will not be sufficient to fund its planned operations for at least one year from the issuance date of the financial statements, and substantial doubt as to the Company's ability to continue as a going concern exists. This forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of expenses could vary materially and adversely as a result of a number of factors.

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

2. Financings

2021 Loan and Security Agreement

On August 6, 2021, the Company entered into a Loan and Security Agreement, or the Loan and Security Agreement, with Silicon Valley Bank and affiliates of Silicon Valley Bank, or collectively, SVB. The Loan and Security Agreement provided for an initial term loan of $25.0 million funded at the closing, or the Term A Tranche, with an additional tranche of $25.0 million available if certain funding and clinical milestones were met by August 31, 2022, or the Term B Tranche.

Effective December 28, 2021, the Company, entered into a First Amendment to the Loan and Security Agreement. We refer to the Loan and Security Agreement, as so amended, as the Amended Loan and Security Agreement.

The Amended Loan and Security Agreement extended the interest-only period through August 31, 2022. Certain milestones specified in the Amended Loan and Security Agreement were not met by the Company on or prior to August 31, 2022, and therefore, the interest-only period was not extended beyond August 31, 2022. The Amended Loan and Security Agreement also eliminated the Term B Tranche, which remained unfunded, leaving only the Term A Tranche, or the SVB Facility. Under the Amended Loan and Security Agreement, the SVB Facility will mature on August 1, 2023.

Refer to Note 4, *Debt,* for further discussion of the Loan and Security Agreement and the Amended Loan and Security Agreement.

2022 Equity Distribution Agreement

On August 12, 2022, the Company entered into an Equity Distribution Agreement, or the Equity Distribution Agreement, with Piper Sandler & Co., or Piper Sandler, pursuant to which the Company can offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $50.0 million through Piper Sandler as its sales agent in an "at the market offering." Piper Sandler will receive a commission of 3.0% of the gross proceeds of any common stock sold under the Equity Distribution Agreement. During the year ended December 31, 2022, there have been no sales of the Company's common stock under the Equity Distribution Agreement.

2022 Public Offering

On November 29, 2022, the Company entered into an underwriting agreement, or the Underwriting Agreement, with Cantor Fitzgerald & Co., or the Underwriter, as the sole underwriter, relating to the issuance and sale in an underwritten offering, or the Offering, of 24,228,719 shares, or the Firm Shares, of the Company’s common stock to the Underwriter at a price of $0.6191 per share.

The net proceeds to the Company from the Offering were $14.7 million (before accounting for the partial exercise of the Underwriter's option as described below) after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Under the terms of the Underwriting Agreement, the Company granted the Underwriter an option, exercisable for 30 days, to purchase up to an additional 3,634,307 shares of common stock, which we refer to, together with the Firm Shares, as the Shares, at the same price per share as the Firm Shares. On January 5, 2023, the Underwriter partially exercised its option to purchase 216,294 shares of common stock.

All of the Shares sold in the Offering were sold by the Company.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Although the Company regularly assesses these estimates, actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

The Company's most significant estimates and judgments used in the preparation of the financial statements are:

- Clinical trial expenses and other research and development expenses;
- Collaboration agreements;
- Fair value measurements of stock-based compensation; and
- Income taxes.

Subsequent Events

The Company evaluated all events and transactions that occurred after the balance sheet date through the date of this Annual Report on Form 10-K. The Company did not have any material subsequent events that impacted its financial statements or disclosures.

Cash and Cash Equivalents

Cash equivalents consist primarily of demand deposit accounts, certificates of deposit and deposits in short-term U.S. treasury money market mutual funds. Cash equivalents are stated at cost, which approximates fair market value.

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Expenditures for maintenance and repairs are charged to expense while the costs of significant improvements are capitalized. Depreciation and amortization is calculated on a straight-line basis using the following periods, which represent the estimated useful lives of the assets:

Office and computer equipment	3 years
Software	3 years
Laboratory equipment	5 years
Leasehold improvements	Life of the lease

Costs, including certain design, construction and installation costs related to assets that are under construction and are in the process of being readied for their intended use, are recorded as construction in progress and are not depreciated until such time as the subject asset is placed in service. Repairs and maintenance that do not extend the useful life of the asset are expensed as incurred. Upon sale, retirement or other disposition of these assets, the costs and related accumulated depreciation are removed from the respective accounts and any gain or loss on the disposition is included in the Statements of Operations.

Long-Lived Assets

Assessments of long-lived assets and the remaining useful lives of such long-lived assets are reviewed for impairment whenever a triggering event occurs or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An asset, or group of assets, is considered to be impaired when the undiscounted estimated net cash flows expected to be generated by the asset, or group of assets, are less than its carrying amount. The impairment recognized is the amount by which the carrying amount exceeds the fair market value of the impaired asset, or group of assets, based on the present value of the expected future cash flows associated with the use of the asset.

Operating Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the Company's chief operating decision maker, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Warrants

The Company assesses whether warrants issued require accounting as derivatives. The Company determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with Financial Accounting Standards Board, or FASB, ASC Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders' equity.

Fair Value Measurements

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements.

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; 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—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value on a recurring and nonrecurring basis as of December 31, 2022 and 2021 are as follows:

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	**Balance as of December 31, 2022**	**Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Cash equivalents	$ 38,058	$ 38,058	$ —	$ —

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	**Balance as of December 31, 2021**	**Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Cash equivalents	$ 75,222	$ 75,222	$ —	$ —

The cash equivalents represent demand deposit accounts and deposits in a short-term United States treasury money market mutual fund quoted in an active market and classified as a Level 1 asset. There have been no changes to the valuation methods during the years ended December 31, 2022 and 2021. The Company had no financial assets or liabilities that were classified as Level 2 or Level 3 during the years ended December 31, 2022 and 2021.

Fair value of non-financial instruments

The Company evaluates its assets for impairment whenever events or changes in circumstances indicate that indicators of impairment exist. In those evaluations, the Company compares estimated future undiscounted cash flows generated by each asset (or asset group) to the carrying value of the asset (or asset group) to determine if an impairment charge is required. If the undiscounted cash flows test fails, the Company estimates the fair value of the asset (or asset group) to determine the impairment.

During 2021, following the Company's strategic restructuring and further cost reduction initiatives, the Company determined that changes in the intended use of its Boston office represented an indicator of impairment, resulting in an impairment charge of $0.6 million to the right-of-use asset. In addition, the Company impaired approximately $0.1 million of leasehold improvements and various other assets associated with its decision to close the Company's Boston office. Refer to Note 8, *Leases,* for further details.

Revenue Recognition from Collaboration Agreements

Revenue for the year ended December 31, 2022 consisted of $2.9 million and for the year ended December 31, 2021 consisted of $0.4 million. For the years ended December 31, 2022 and 2021, the Company recognized revenue through its Collaboration Agreement with Solasia Pharma K.K. primarily due to the achievement of milestones, as further described in Note 9, *Commitments and Contingencies.*

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

The Company primarily generates revenue through collaboration arrangements with strategic partners for the development and commercialization of product candidates. The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers, or* ASC 606. The core principle of ASC 606 is that an entity should recognize revenue to depict the transfer of promised goods and/or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and/or services. To determine the appropriate amount of revenue to be recognized for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following steps: (i) identify the contract(s) with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when (or as) each performance obligation is satisfied.

The Company recognizes collaboration revenue under certain of the Company's license or collaboration agreements that are within the scope of ASC 606. The Company's contracts with customers typically include promises related to licenses to intellectual property, research and development services and options to purchase additional goods and/or services. 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 recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees.

Contracts that include an option to acquire additional goods and/or services are evaluated to determine if such option provides a material right to the customer that it would not have received without entering into the contract. If so, the option is accounted for as a separate performance obligation. If not, the option is considered a marketing offer which would be accounted for as a separate contract upon the customer's election.

The terms of the Company's arrangements with customers typically include the payment of one or more of the following:(i) non-refundable, up-front payment, (ii) development, regulatory and commercial milestone payments, (iii) future options and (iv) royalties on net sales of licensed products. Accordingly, the transaction price is generally comprised of a fixed fee due at contract inception and variable consideration in the form of milestone payments due upon the achievement of specified events and tiered royalties earned when customers recognize net sales of licensed products. The Company measures the transaction price based on the amount of consideration to which it expects to be entitled in exchange for transferring the promised goods and/or services to the customer. The Company utilizes the most likely amount method to estimate the amount of variable consideration, to predict the amount of consideration to which it will be entitled. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes development and regulatory milestone payments, the Company evaluates whether the associated event is considered probable of achievement and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Company or the licensee, such as those dependent upon receipt of regulatory approval, are not considered to be probable of achievement until the triggering event occurs. At the end of each reporting period, the Company reevaluates the probability of achievement of each milestone and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment. For arrangements that include sales-based royalties, including milestone payments based upon the achievement of a certain level of product sales, the Company recognizes revenue upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). Consideration that would be received for optional goods and/or services is excluded from the transaction price at contract inception.

The Company allocates the transaction price to each performance obligation identified in the contract on a relative standalone selling price basis. However, certain components of variable consideration are allocated specifically to one or more particular performance obligations in a contract to the extent both of the following criteria are met: (i) the terms of the payment relate specifically to the efforts to satisfy the performance obligation or transfer the distinct good or service and (ii) allocating the variable amount of consideration entirely to the performance obligation or the distinct good or service is consistent with the allocation objective of the standard whereby the amount allocated depicts the amount of consideration to which the entity expects to be entitled in exchange for transferring the promised goods or services. The Company develops assumptions that require the use of judgment to determine the standalone selling price for each performance obligation identified in each contract. The key assumptions utilized in determining the standalone selling price for each performance obligation may include forecasted revenue, development timelines, estimated research and development costs, discount rates, likelihood of exercise and probabilities of technical and regulatory success.

Revenue is recognized based on the amount of the transaction price that is allocated to each respective performance obligation when or as the performance obligation is satisfied by transferring a promised good and/or service to the customer. For performance obligations that are satisfied over time, the Company recognizes revenue by measuring the progress toward complete satisfaction of the performance obligation

using a single method of measuring progress which depicts the performance in transferring control of the associated goods and/or services to the customer. The Company uses input methods to measure the progress toward the complete satisfaction of performance obligations satisfied over time. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.

Research and Development Costs

As part of the process of preparing the Company's financial statements, the Company is required to estimate its accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with its personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the services when the Company has not yet been invoiced or otherwise notified of the actual costs. The majority of the Company's service providers invoice the Company in arrears for services performed, on a predetermined schedule or when contractual milestones are met; however, a few require advanced payments. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known to it at that time. Examples of estimated accrued research and development expenses include fees paid to:

- clinical research organizations, or CROs, in connection with performing research services on its behalf and clinical trials;
- investigative sites or other providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing, development, and distribution of preclinical and clinical supplies.

The Company bases its expenses related to preclinical studies and clinical trials on its estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct and manage clinical trials on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or amount of prepaid expense accordingly. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low in any particular period. To date, the Company has not made any material adjustments to its prior estimates of accrued research and development expenses.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences of temporary differences between the financial statement carrying amounts and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. The Company evaluates the realizability of its deferred tax assets and establishes a valuation allowance when it is more likely than not that all or a portion of deferred tax assets will not be realized.

The Company accounts for uncertain tax positions using a “more-likely-than-not” threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates this tax position on an annual basis. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense (Refer to Note 12, *Income Taxes*).

Accounting for Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the estimated fair value of the award and is recognized as expense over the employee’s requisite service period. Stock-based compensation expense is based on the number of awards ultimately expected to vest and is reduced for forfeitures as they occur. Consistent with prior years, the Company uses the Black-Scholes option pricing model, which requires estimates of the expected term option holders will retain their options before exercising them and the estimated volatility of the Company’s common stock price over the expected term.

The Company recognized the full impact of its share-based employee payment plans in the Statements of Operations for each of the years ended December 31, 2022 and 2021 and did not capitalize any such costs on the Balance Sheets. The Company recognized $3.0 million of compensation expense related to stock options for the year ended December 31, 2022 and $7.4 million of compensation expense related to stock options for the year ended December 31, 2021. The Company recognized $0.5 million of compensation expense, related to restricted stock for the year ended December 31, 2022 and $3.4 million for the year ended December 31, 2021 (refer to Note 13, *Stock Option Plan*). The total compensation expense relating to vesting of stock options and restricted stock awards for the year ended December 31, 2022 was $3.5 million and $10.8 million for the year ended December 31, 2021. The following table presents share-based compensation expense included in the Company's Statements of Operations:

	Year Ended December 31,	
(in thousands)	2022	2021
Research and development	868	2,598
General and administrative	2,660	8,176
Stock-based compensation expense	$ 3,528	$ 10,774

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. The estimated weighted-average fair value of stock options granted to employees in the year ended December 31, 2022 was approximately $0.77 per share and was approximately $2.62 per share for the year ended December 31, 2021. Assumptions regarding volatility, expected term, dividend yield and risk-free interest rate are required for the Black-Scholes model. The volatility assumption is based on the Company's historical experience. The risk-free interest rate is based on a U.S. treasury note with a maturity similar to the option award's expected life. The expected life represents the average period of time that options granted are expected to be outstanding. The Company calculated expected term using the simplified method described in SEC Staff Accounting Bulletin, or SAB, No. 107 and No. 110 as it continues to meet the requirements promulgated in SAB No. 110. The assumptions for volatility, expected life, dividend yield and risk-free interest rate are presented in the table below:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	1.63 – 4.21%	0.50 – 1.36%
Expected life in years	5.27 – 6.25	5.50 – 6.25
Expected volatility	74.49 – 88.75%	72.53 – 74.80%
Expected dividend yield	—%	—%

Net Loss per Share

Basic net loss per common share is computed by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period, plus the dilutive effect of outstanding options and warrants, using the treasury stock method and the average market price of the Company's common stock during the applicable period, unless their effect on net loss per share is antidilutive. The effect of computing diluted net loss per common share was antidilutive for any potentially issuable shares of common stock from the conversion of stock options, unvested restricted stock and warrants and, as such, have been excluded from the calculation.

The computation of basic and diluted net loss per share consists of the following:

	Year Ended December 31,	
	2022	2021
Net loss	$ (37,730)	$ (78,751)
Weighted-average common shares outstanding, basic and diluted	217,130,311	214,399,074
Net loss per share, basic and diluted	$ (0.17)	$ (0.37)

Certain shares related to some of the Company's outstanding common stock options, unvested restricted stock and warrants have not been included in the computation of diluted net loss per share for the years ended December 31, 2022 and 2021 as the result would be antidilutive. Such potential common shares on December 31, 2022 and 2021 consist of the following:

	December 31,	
	2022	2021
Common stock options	10,408,622	10,665,869
Inducement stock options	-	32,500
Unvested restricted stock	939,062	1,198,580
Warrants	22,922,342	22,922,342
	34,270,026	34,819,291

New Accounting Pronouncements

In November 2021, the FASB issued Accounting Standards Update, or ASU, 2021-10, Government Assistance (Topic 832): Disclosures by Business entities about Government Assistance, which requires business entities to disclose information about certain government assistance that they receive. Entities must comply with the new disclosure requirements if they account for transactions with government entities under the (1) contribution model or (2) grant model by analogy. The Company adopted this standard effective January 1, 2022, with no material impact upon adoption.

In July 2021, the FASB issued ASU 2021-05, Leases (Topic 842): Lessors – Certain Leases with Variable Lease Payments, which requires lessors to classify as operating leases those leases with variable lease payments that do not depend on an index or rate if another classification (i.e. sales-type or direct financing) would result in a commencement date (‘day 1’) selling loss. The Company adopted this standard effective January 1, 2022, with no material impact upon adoption.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt - Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Compensation (Topic 718), and Derivatives and Hedging - Contracts in Entity’s Own Equity (Subtopic 815- 40): Warrant modifications, which clarifies an issuer’s accounting for certain modifications or exchanges of freestanding equity-classified written call options (e.g. warrants) that remain equity-classified after modification or exchange. The Company adopted this standard effective January 1, 2022, with no material impact upon adoption.

4. Debt

The carrying values of the Company's debt obligation were as follows:

	December 31,	
($ in thousands)	**2022**	**2021**
Loan and Security Agreement	$ 17,395	$ 25,209
Unamortized discount on Loan and Security Agreement	(630)	(1,091)
Total debt	16,765	24,118
Less: long-term debt, current	(16,765)	(7,868)
Long-term debt	$ —	$ 16,250

On August 6, 2021, the Company entered into the Loan and Security Agreement. The Loan and Security Agreement provided for an initial term loan of $25.0 million funded at the closing, with an additional tranche of $25.0 million available if certain funding and clinical milestones were met by August 31, 2022. On December 28, 2021, the Company entered into the Amended Loan and Security Agreement.

Under the terms of the Amended Loan and Security Agreement, the SVB Facility was modified to eliminate the additional $25.0 million tranche, which remained unfunded, leaving only the initial $25.0 million as the full amount available under the SVB Facility. The SVB Facility bears interest at a floating rate per annum on outstanding loans, payable monthly, at the greater of (a) 7.75% and (b) the current published U.S. prime rate, plus a margin of 4.5%. As of December 31, 2022, interest on the outstanding loans was 12.00%. The Amended Loan and Security Agreement provided for an interest-only period through August 31, 2022. Commencing on September 1, 2022, aggregate outstanding borrowings became repayable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding obligations under the Amended Loan and Security Agreement are due and payable on August 1, 2023. The Company will also owe SVB 5.75% of the original principal amounts borrowed as a final payment. The Company is permitted to make up to two prepayments, subject to a prepayment premium of the amount being prepaid, ranging from 1.00% to 2.00%, of the SVB Facility, each such prepayment to be at least $5.0 million plus all accrued and unpaid interest on the portion being prepaid.

As a result of not achieving certain milestones specified in the Amended Loan and Security Agreement on or prior to August 31, 2022, the Company was required to cash collateralize half of the sum of the then-outstanding principal amount of the SVB Facility, plus an amount equal to 5.75% of the original principal amount of the SVB Facility. As of December 31, 2022, the Company has collateralized $13.9 million, which is classified as restricted cash on the Balance Sheet. So long as no event of default has occurred and subject to certain other terms related to the remaining outstanding balance under the SVB Facility being satisfied, $2.5 million will be released from the collateral account following the eighth scheduled payment of principal and interest, and a further $4.0 million will be released following the tenth scheduled payment of principal and interest. The SVB Facility and related obligations under the Amended Loan and Security Agreement are secured by substantially all of the Company's properties, rights and assets, except for its intellectual property (which is subject to a negative pledge under the Amended Loan and Security Agreement). In addition, the Amended Loan and Security Agreement contains customary representations, warranties, events of default and covenants.

In connection with its entry into the Loan and Security Agreement, the Company issued to SVB warrants to purchase (i) up to 432,844 shares of the Company's common stock, in the aggregate, and (ii) up to an additional 432,842 shares of common stock, in the aggregate, in the event the Company achieved certain clinical milestones, in each case at an exercise price per share of $2.22.

In connection with its entry into the Amended Loan and Security Agreement, the Company amended and restated the warrants issued to SVB. As amended and restated, the warrants are for up to 649,615 shares of the Company's common stock, in the aggregate, at an exercise price per share of $1.16, or the SVB Warrants. The SVB Warrants expire on August 6, 2031.

The issuance costs for the Loan and Security Agreement, including the Amended Loan and Security Agreement, were approximately $1.2 million and primarily related to the warrants issued to SVB, which will be amortized into interest expense over the period to August 1, 2023. Interest expense, including the amortization of issuance costs, was $3.2 million for the year ended December 31, 2022 and $1.2 million for the year ended December 31, 2021.

The fair value of the Amended Loan and Security Agreement as of December 31, 2022 approximates its face value.

5. Property and Equipment, net

Property and equipment, net, consists of the following:

	December 31,	
($ in thousands)	**2022**	**2021**
Office and computer equipment	$ 2,183	$ 2,534
Software	1,291	1,236
Leasehold improvements	9,561	9,474
Laboratory equipment	5,232	5,110
	18,267	18,354
Less: accumulated depreciation	(9,807)	(7,413)
Property and equipment, net	$ 8,460	$ 10,941

Depreciation expense for the year ended December 31, 2022 was $2.8 million and was $2.6 million for the year ended December 31, 2021. During the year ended December 31, 2021, the Company impaired property and equipment by $0.1 million. Refer to Note 3, *Summary of Significant Accounting Policies*, for further details.

6. Accrued Expenses

Accrued expenses consist of the following:

($ in thousands)	**2022**	**2021**
Clinical	$ 2,200	$ 1,677
Employee compensation	1,160	1,922
Professional services	534	825
Preclinical services	198	363
Manufacturing services	1,177	1,056
Other consulting services	16	66
Other	169	167
	$ 5,454	$ 6,076

7. Related Party Transactions

Collaboration with Vineti Inc.

On July 9, 2020, the Company entered into a master service agreement and statement of work with Vineti, Inc., or Vineti. Pursuant to the agreements, Vineti is developing a software platform to coordinate and orchestrate the order, cell collection and manufacturing process for the Company's T-cell therapy, or TCR-T, clinical programs. Heidi Hagen, who became a director of the Company in June 2019 and resigned November 2, 2021 and was appointed the Company's interim Chief Executive Officer on February 25, 2021 and resigned on August 30, 2021, is a co-founder and former officer, of Vineti. During the year ended December 31, 2022, the Company did not incur expenses for services performed by Vineti, compared to $0.4 million during the year ended December 31, 2021.

WaterMill Settlement Agreement

On February 4, 2021, the Company entered into an agreement, or the Settlement Agreement, with WaterMill Asset Management Corp. and Robert W. Postma, or collectively, the WaterMill Parties. Pursuant to the Settlement Agreement, the Company increased the size of its board of directors from eight to nine directors and appointed Mr. Postma to fill the newly created directorship.

In accordance with the Settlement Agreement, the Company agreed to reimburse the WaterMill Parties for up to $0.4 million of their reasonable out-of-pocket expenses in connection with (i) the WaterMill Parties' solicitation of written consents from our stockholders to vote in favor of certain proposals, as set forth in the definitive consent statement filed by the WaterMill Parties on October 30, 2020, and (ii) the negotiation, execution, and effectuation of the Settlement Agreement. As of February 19, 2021, the Company has fully reimbursed the WaterMill Parties an aggregate amount of $0.4 million.

Joint Venture with TriArm Therapeutics/Eden BioCell

On December 18, 2018, the Company and TriArm Therapeutics, Ltd., or TriArm, launched Eden BioCell, Ltd., or Eden BioCell, as a joint venture to lead commercialization of the Company's *Sleeping Beauty*-generated CAR-T therapies in the People's Republic of China (including Macau and Hong Kong), Taiwan and Korea. The Company licensed to Eden BioCell the rights in Greater China for its third-generation *Sleeping Beauty*-generated CAR-T therapies targeting the CD19 antigen. Eden BioCell is owned equally by the Company and TriArm and the parties share decision-making authority. TriArm has contributed $10.0 million to Eden BioCell and has committed up to an additional $25.0 million to this joint venture. TriArm also manages all clinical development in the territory pursuant to a master services agreement between TriArm and Eden BioCell. James Huang was the founder and serves as managing partner of Panacea Venture, which is an investor in TriArm. Mr. Huang is the Chair of the Company's board of directors and has been a director since July 2020. He also serves as a member of Eden BioCell's board of directors.

For the years ended December 31, 2022 and 2021, Eden BioCell incurred a net loss and the Company continues to have no commitment to fund its operations. In September 2021, TriArm and Alaunos mutually agreed to dissolve the Eden BioCell joint venture. The joint venture agreement has been terminated and the Eden BioCell entity is in the process of being dissolved. Refer to Note 15, *Joint Venture*, for further details.

8. Leases

Operating Leases

In June 2012, the Company entered into a master lease for the Company's office in Boston, Massachusetts, which was originally set to expire in August 2016, but was renewed through August 31, 2021. On April 22, 2021, the Company extended its lease for a portion of office space in Boston. The renewal of the portion of the Company's office space was originally set to expire on August 31, 2021, but was extended through August 31, 2026. As of December 31, 2022, and December 31, 2021, a total security deposit of $0.1 million is included in deposits on the Company's balance sheet. In December 2021, the Company made the decision to move its operations away from its former corporate office in Boston. As described in Note 3, *Summary of Significant Accounting Policies,* the Company's change in the intended use of the Boston office represented an indicator of impairment. The Company determined the aggregate carrying value of the asset group (approximately $1.4 million as of December 31, 2021) was in excess of the aggregate estimated fair value and recorded an impairment charge of $0.6 million to the right-of-use asset and approximately $0.1 million to associated property and equipment during the year ended December 31, 2021. The fair value was determined based on the amount and timing of estimated net future cash flows, discounted at a risk-adjusted rate of 10%.

On March 12, 2019, the Company entered into a lease agreement for office and lab space in Houston, Texas at MD Anderson through April 2021. Under the terms of the lease agreement, the Company leases approximately 1,038 square feet and was required to make rental payments

at an average monthly rate of approximately $2 thousand through April 2021. On October 15, 2019, the Company entered into a lease agreement for additional office and laboratory space in Houston through February 2027. Under the terms of the lease, the Company leases from MD Anderson, approximately 8,443 square feet and is initially required to make rental payments of approximately $17 thousand per month through February 2027, subject to an annual base rent increase of approximately 3.0% throughout the term. Effective April 7, 2020, the Company leased an additional 5,594 square feet from MD Anderson. The Company is initially required to make rental payments of approximately $12 thousand per month through February 2027, subject to an annual base rent increase of approximately 3.0% throughout the term.

On December 15, 2020, the Company entered into a second agreement with MD Anderson to lease additional space on MD Anderson's campus (the "2020 Lease"). The Company is initially required to make rental payments of approximately $37 thousand per month through April 2028, subject to an annual base rent increase of approximately 3.0% throughout the term beginning in April 2023. The 2020 Lease may be extended for one additional five-year term at the Company's election.

In April 2022, the Company modified the 2020 Lease, which reduced the Company's leased space from 18,111 square feet to 3,228 square feet. As a result, the associated lease liability and right-of-use asset were remeasured to $0.4 million based on revised lease payments. A gain of $0.1 million was recorded on the lease modification during the year ended December 31, 2022. The Company is initially required to make payments of approximately $7 thousand per month through April 2028, subject to an annual base rent increase of approximately 3.0% throughout the term. The 2020 Lease may be extended for one additional five-year term at the Company's election.

The components of lease expense were as follows:

	Year Ended December 31,	
($ in thousands)	**2022**	**2021**
Operating lease cost	$ 756	$ 1,394
Total lease cost	$ 756	$ 1,394
Weighted-average remaining lease term (years)	4.13	5.58
Weighted-average discount rate	8.26%	8.00%

The Company paid $0.8 million for amounts included in the measurement of the lease liabilities for the year-ended December 31, 2022. The Company did not recognize new operating lease assets obtained in exchange for operating lease liabilities for the year-ended December 31, 2022.

As of December 31, 2022, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Maturity of Lease Liabilities	Operating Leases
2023	757
2024	780
2025	804
2026	712
2027	158
Thereafter	31
Total lease payments	3,242
Less: imputed interest	(496)
Present value of lease payments	$ 2,746

In June 2022, the Company executed an agreement to sub-sublease 4,772 square feet of subleased office space in Boston. The term of the sub-sublease is from July 1, 2022 to June 30, 2025 and provides the sub-subtenant with an option to extend through to July 31, 2026. For the year ended December 31, 2022, the Company recognized $0.1 million in lease income, which is classified within other income (expense), net in the Statement of Operations. Under the current terms of the agreement, lease income for the remainder of the sub-sublease term is expected to be $0.2 million in 2023, $0.2 million in 2024 and $0.1 million in 2025.

9. Commitments and Contingencies

Exclusive License Agreement with PGEN Therapeutics

On October 5, 2018, the Company entered into an exclusive license agreement, or License Agreement, with PGEN Therapeutics, or PGEN, a wholly owned subsidiary of Precigen Inc., or Precigen, which was formerly known as Intrexon Corporation. Pursuant to the terms of the

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

License Agreement, the Company has exclusive, worldwide rights to research, develop and commercialize (i) TCR products designed for neoantigens for the treatment of cancer, (ii) products utilizing Precigen's RheoSwitch gene switch, or RTS, for the treatment of cancer, referred to as IL-12 Products and (iii) CAR products directed to (A) CD19 for the treatment of cancer, referred to as CD19 Products, and (B) BCMA for the treatment of cancer, subject to certain obligations to pursue such target under the License and Collaboration Agreement effective March 27, 2015 between us, Precigen and ARES TRADING S.A., a subsidiary of Merck KGaA, as assigned by Precigen to PGEN. Under the License Agreement, the Company also has exclusive, worldwide rights for certain patents relating to the *Sleeping Beauty* technology to research, develop and commercialize TCR products for both neoantigens and shared antigens for the treatment of cancer, referred to as TCR Products.

The Company is solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. The Company is required to use commercially reasonable efforts, as defined in the License Agreement, to develop and commercialize IL-12 products, CD19 products and TCR Products.

In consideration of the licenses and other rights granted by PGEN, the Company pays PGEN an annual license fee of $0.1 million and the Company reimbursed PGEN for certain historical costs of the licensed programs.

The Company will make milestone payments totaling up to an additional $52.5 million for each exclusively licensed program upon the initiation of later stage clinical trials and upon the approval of exclusively licensed products in various jurisdictions. In addition, the Company will pay PGEN tiered royalties ranging from low-single digits to high-single digits on the net sales derived from the sale of any approved IL-12 products and CAR products. The Company will also pay PGEN royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of any approved TCR products, up to a maximum royalty amount of $100.0 million in the aggregate. The Company will also pay PGEN 20% of any sublicensing income received by us relating to the licensed products. The Company is responsible for all development costs associated with each of the licensed products.

PGEN will pay the Company royalties ranging from low-single digits to mid-single digits on the net sales derived from the sale of PGEN's CAR products, up to a maximum royalty amount of $100.0 million. No royalty amounts were incurred during the years ended December 31, 2022 and 2021.

In October 2020, the Company entered into an amendment to the License Agreement relating to the transfer of certain materials and PGEN's obligations to provide transition assistance relating to the IL-12 products.

License Agreement and 2015 Research and Development Agreement —The University of Texas MD Anderson Cancer Center

On January 13, 2015, the Company, together with Precigen, entered into the MD Anderson License with MD Anderson (which Precigen subsequently assigned to PGEN). Pursuant to the MD Anderson License, the Company, together with PGEN, holds an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson, including technologies relating to novel CAR T-cell therapies, non-viral gene transfer systems, genetic modification and/or propagation of immune cells and other cellular therapy approaches, Natural Killer, or NK Cells, and TCRs, arising from the laboratory of Laurence Cooper, M.D., Ph.D., who served as the Company's Chief Executive Officer from May 2015 until February 2021 and was formerly a tenured professor of pediatrics at MD Anderson.

On August 17, 2015, the Company, Precigen and MD Anderson entered into the 2015 R&D Agreement to formalize the scope and process for the transfer by MD Anderson, pursuant to the terms of the MD Anderson License, of certain existing research programs and related technology rights, as well as the terms and conditions for future collaborative research and development of new and ongoing research programs. The rights and obligations of Precigen under the 2015 R&D Agreement were assigned to the Company pursuant to the Fourth Amendment to 2015 R&D Agreement which was entered into on September 19, 2019 (the "Fourth Amendment") with an effective date of October 5, 2018. The activities under the 2015 R&D Agreement are directed by a joint steering committee comprised of two members from the Company and one member from MD Anderson.

As provided under the MD Anderson License, the Company provided funding for research and development activities in support of the research programs under the 2015 R&D Agreement for a period of three years and in an amount of no less than $15.0 million and no greater than $20.0 million per year. On November 14, 2017, the Company entered into an amendment to the 2015 R&D Agreement, extending its term until April 15, 2021. In connection with the execution of the 2019 R&D Agreement described below, on October 22, 2019, the Company amended the 2015 R&D Agreement to extend the term of the 2015 R&D Agreement until December 31, 2026 and to allow cash resources on hand at MD Anderson under the 2015 R&D Agreement to be used for development costs under the 2019 Research and Development Agreement, or the 2019 R&D Agreement, which we entered into on October 22, 2019, with MD Anderson, pursuant to which we agreed to collaborate with respect to the TCR program.

The term of the MD Anderson License expires on the last to occur of (a) the expiration of all patents licensed thereunder, or (b) the twentieth anniversary of the date of the MD Anderson License; provided, however, that following the expiration of the term of the MD Anderson

License, the Company, together with Precigen, shall then have a fully-paid up, royalty free, perpetual, irrevocable and sublicensable license to use the licensed intellectual property thereunder. After ten years from the date of the MD Anderson License and subject to a 90-day cure period, MD Anderson will have the right to convert the MD Anderson License into a non-exclusive license if the Company and Precigen are not using commercially reasonable efforts to commercialize the licensed intellectual property on a case-by-case basis. After five years from the date of the MD Anderson License and subject to a 180-day cure period, MD Anderson will have the right to terminate the MD Anderson License with respect to specific technology(ies) funded by the government or subject to a third-party contract if the Company and Precigen are not meeting the diligence requirements in such funding agreement or contract, as applicable. MD Anderson may also terminate the agreement with written notice upon material breach by the Company and Precigen, if such breach has not been cured within 60 days of receiving such notice. In addition, the MD Anderson License will terminate upon the occurrence of certain insolvency events for both the Company and Precigen and may be terminated by the mutual written agreement of the Company, PGEN, and MD Anderson.

2019 Research and Development Agreement—The University of Texas MD Anderson Cancer Center

Under the 2019 R&D Agreement, the Company and MD Anderson will, among other things, collaborate on programs to expand the Company's TCR library and conduct clinical trials. The activities under the 2019 R&D Agreement are directed by a joint steering committee comprised of two members from the Company and one member from MD Anderson.

The Company will own all inventions and intellectual property developed under the 2019 R&D Agreement and the Company will retain all rights to all, intellectual property, patentable or not, for oncology products manufactured using non-viral gene transfer technologies under the 2019 R&D Agreement, including the Company's *Sleeping Beauty* technology. The Company has granted MD Anderson an exclusive license for such intellectual property to develop and commercialize autologous TCR products manufactured using viral gene transfer technologies, and any products outside the field of oncology and a non-exclusive license for allogenic TCR products manufactured using viral-based technologies.

Under the 2019 R&D Agreement, the Company agreed, beginning on January 1, 2021, to reimburse MD Anderson up to a total of $20.0 million for development costs under the 2019 R&D Agreement, after the funds from the 2015 R&D Agreement are exhausted. In addition, the Company will pay MD Anderson royalties on net sales of its TCR products. The Company is required to make performance-based payments upon the successful completion of clinical and regulatory benchmarks relating to its TCR products. The aggregate potential benchmark payments are $36.5 million, of which only $3.0 million will be due prior to the first marketing approval of the Company's TCR products. The royalty rates and benchmark payments owed to MD Anderson may be reduced upon the occurrence of certain events. The Company also agreed to sell its TCR products to MD Anderson at preferential prices and will sell the Company's TCR products in Texas exclusively to MD Anderson for a limited period of time following the first commercial sale of the Company's TCR products. For the year ended December 31, 2022, the Company incurred clinical expenses of $0.8 million from MD Anderson related to this agreement, compared to $0.3 million for the year ended December 31, 2021.

The 2019 R&D Agreement will terminate on December 31, 2026 and either party may terminate the 2019 R&D Agreement following written notice of a material breach. The 2019 R&D Agreement also contains customary provisions related to indemnification obligations, confidentiality and other matters.

In connection with the execution of the 2019 R&D Agreement, on October 22, 2019, the Company issued MD Anderson a warrant to purchase 3,333,333 shares of the Company's common stock, which is referred to as the MD Anderson Warrant. The MD Anderson Warrant has an initial exercise price of $0.001 per share, expires on December 31, 2026, and vests in four parts upon the occurrence of certain clinical milestones. As of December 31, 2022, the milestones have not been met.

License Agreement with the NCI

On May 28, 2019, the Company entered into a patent license agreement, or the Patent License, with the NCI. Pursuant to the Patent License, the Company holds an exclusive, worldwide license to certain intellectual property to develop and commercialize patient-derived (autologous), peripheral blood T-cell therapy products engineered by transposon-mediated gene transfer to express TCRs reactive to mutated *KRAS, TP53* and *EGFR* neoantigens. In addition, pursuant to the Patent License, the Company holds an exclusive, worldwide license to certain intellectual property for manufacturing technologies to develop and commercialize autologous, peripheral blood T-cell therapy products engineered by non-viral gene transfer to express TCRs, as well as a non-exclusive, worldwide license to certain additional manufacturing technologies. On May 29, 2019, January 8, 2020, September 28, 2020, April 16, 2021, May 4, 2021 and August 13, 2021 the Company amended the Patent License to expand its TCR library to include additional TCRs reactive to mutated *KRAS* and *TP53* neoantigens licensed from the NCI.

The terms of the Patent License require the Company to pay the NCI minimum annual royalties in the amount of $0.3 million, which amount will be reduced to $0.1 million once the aggregate minimum annual royalties paid by the Company equals $1.5 million.

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The Company is also required to make performance-based payments upon successful completion of clinical and regulatory benchmarks relating to the licensed products. Of such payments, the aggregate potential benchmark payments are $4.3 million, of which aggregate payments of $3.0 million are due only after marketing approval in the United States or in Europe, Japan, Australia, China or India. The first benchmark payment of $0.1 million was paid during the year ended December 31, 2022 upon the initiation of the Company's TCR-T Library Phase 1/2 Trial, which was a qualifying Phase 1 clinical trial under the terms of the Patent License.

In addition, the Company is required to pay the NCI one-time benchmark payments following aggregate net sales of licensed products at certain aggregate net sales ranging from $250.0 million to $1.0 billion. The aggregate potential amount of these benchmark payments is $12.0 million. The Company must also pay the NCI royalties on net sales of products covered by the Patent License at rates in the low to mid-single digits depending upon the technology included in a licensed product. To the extent the Company enters into a sublicensing agreement relating to a licensed product, the Company is required to pay the NCI a percentage of all consideration received from a sublicensee, which percentage will decrease based on the stage of development of the licensed product at the time of the sublicense.

The Patent License will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. The NCI may terminate or modify the Patent License in the event of a material breach, including if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the Patent License, or any portion thereof, in the Company's sole discretion at any time upon 60 days' written notice to the NCI. In addition, the NCI has the right to: (i) require the Company to sublicense the rights to the product candidates covered by the Patent License upon certain conditions, including if the Company is not reasonably satisfying required health and safety needs and (ii) terminate or modify the Patent License, including if the Company is not satisfying requirements for public use as specified by federal regulations.

For the year ended December 31, 2022 the Company incurred $0.7 million of expenses and incurred $0.5 million of expenses for the year ended December 31, 2021.

Cooperative Research and Development Agreement (CRADA) with the NCI

On January 9, 2017, the Company entered into a Cooperative Research and Development Agreement, or the CRADA, with the NCI. The purpose of this collaboration was to advance a personalized TCR-T approach for the treatment of solid tumors. Using the Company's *Sleeping Beauty* technology, the NCI would analyze a patient's own cancer cells, identify their unique neoantigens and TCRs reactive against those neoantigens and then use the Company's *Sleeping Beauty* technology to transpose one or more TCRs into T cells for re-infusion. Research conducted under the CRADA will be at the direction of Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI, in collaboration with the Company's researchers.

The Company is responsible for providing the NCI with the test materials necessary for them to conduct their studies, and eventually, clinical trials pursuant to the CRADA. Inventions, data and materials discovered or produced in connection with performance of the research plan under the CRADA will remain the sole property of the party who produced the discovery. The parties will jointly own all inventions jointly discovered under the research plan. The owner of any invention under the CRADA will make the decision to file a patent covering the invention, or in the case of a jointly owned invention, the Company will have the first opportunity to file a patent covering the invention. If the Company fails to provide timely notice of its decision to the NCI or decides not to file a patent covering the joint invention, the NCI has the right to make the filing. For any invention solely owned by the NCI or jointly made by the NCI and the Company for which a patent application was filed, the U.S. Public Health service grants the Company an exclusive option to elect an exclusive or non-exclusive commercialization license. For inventions owned solely by the NCI or jointly owned by the NCI and the Company, which are licensed according to the terms described above, the Company agreed to grant to the U.S. government a non-exclusive, non-transferable, irrevocable and paid up license to practice the invention or have the invention practiced on its behalf throughout the world. The Company is also required to grant the U.S. government a non-exclusive, non-transferable, irrevocable and paid up license to practice the invention or have the invention practiced on its behalf throughout the world for any of the Company's solely owned inventions. The agreement may be terminated by any of the parties upon 60 days prior written consent.

The NCI has a cleared Investigational New Drug Application, or IND, that would permit them to begin this trial. To the Company's knowledge, the trial has not yet enrolled. The progress and timeline for this trial, including the timeline for dosing patients, are under control of the NCI.

In February 2019, the Company extended the CRADA with the NCI until January 9, 2022, committing an additional $5.0 million to this program; however, for the third and fourth quarters of 2021, the Company was not required to make payments toward the program as agreed with the NCI. Therefore, as of December 31, 2022, the Company made $3.8 million of payments under the February 2019 CRADA extension, and the NCI has agreed that this is full satisfaction of the agreement and no further payments are due under the $5.0 million commitment. In March 2022, the Company entered into an amendment to the CRADA that was retroactive, effective January 9, 2022 to extend the term of the

CRADA until January 9, 2023. In June 2022, the Company entered into the Fourth Amendment to the CRADA, or the CRADA Fourth Amendment, which, among other things, extended the term of the CRADA until January 9, 2025. In connection with the CRADA Fourth Amendment, the Company agreed to contribute $1.0 million per year, payable on a quarterly basis, beginning in the first quarter of 2023. The Company did not incur expenses under the CRADA for the year ended December 31, 2022, as compared to $1.3 million for the year ended December 31, 2021.

Patent and Technology License Agreement—The University of Texas MD Anderson Cancer Center and the Texas A&M University System

On August 24, 2004, the Company entered into a patent and technology license agreement with MD Anderson and the Texas A&M University System, which the Company refers to, collectively, as the Licensors. Under this agreement, the Company was granted an exclusive, worldwide license to rights (including rights to U.S. and foreign patent and patent applications and related improvements and know-how) for the manufacture and commercialization of two classes of organic arsenicals (water- and lipid-based) for human and animal use. The class of water-based organic arsenicals includes darinaparsin.

Under the terms of the agreement, the Company may be required to make additional payments to the Licensors upon achievement of certain milestones in varying amounts which, on a cumulative basis could total up to an additional $4.5 million. In addition, the Licensors are entitled to receive royalty payments on sales from a licensed product and will also be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. During the year ended December 31, 2022, $2.5 million was incurred as a one-time milestone payment under the terms of the agreement, compared to $0.1 million for the year ended December 31, 2021. The Company incurred $2 thousand in royalty expenses on sales under this agreement during the year ended December 31, 2022, and did not incur royalty expenses on sales under this agreement during the year ended December 31, 2021.

Collaboration Agreement with Solasia Pharma K.K.

On March 7, 2011, the Company entered into a License and Collaboration Agreement with Solasia Pharma K. K., or Solasia, which was amended on July 31, 2014 to include an exclusive worldwide license and amended on October 14, 2021 to revise certain payment schedule details, or, as so amended, the Solasia License and Collaboration Agreement. Pursuant to the Solasia License and Collaboration Agreement, the Company granted Solasia an exclusive license to develop and commercialize darinaparsin in both intravenous and oral forms and related organic arsenic molecules, in all indications for human use.

As consideration for the license, the Company is eligible to receive from Solasia development- and sales-based milestones, a royalty on net sales of darinaparsin, once commercialized, and a percentage of any sublicense revenue generated by Solasia. Solasia will be responsible for all costs related to the development, manufacturing and commercialization of darinaparsin. The Company’s licensors, as defined in the Solasia License and Collaboration Agreement, will receive a portion of all milestone and royalty payments made by Solasia to the Company in accordance with the terms of the Solasia License and Collaboration Agreement with the licensors, as described above.

In June 2022, Solasia announced that darinaparsin had been approved from relapsed or refractory Peripheral T-Cell Lymphoma by the Ministry of Health, Labor and Welfare in Japan. During the year ended December 31, 2022, the Company earned $2.9 million of collaboration revenue under the Solasia License and Collaboration Agreement primarily related to Solasia's achievement of certain sales-based milestones in Japan, compared to $0.4 million during the year ended December 31, 2021.

10. Warrants

In connection with the Company’s November 2018 private placement that provided net proceeds of approximately $47.1 million, the Company issued warrants to purchase an aggregate of 18,939,394 shares of common stock, which became exercisable six months after the closing of the private placement, or the November 2018 Warrants. The November 2018 Warrants had an exercise price of $3.01 per share and have a five-year term. The fair value of the November 2018 Warrants was estimated at $18.4 million using a Black-Scholes model with the following assumptions: expected volatility of 71%, risk free interest rate of 2.99%, expected life of five years and no dividends.

On July 26, 2019 and September 12, 2019, the Company entered into agreements with existing investors whereby the investors exercised the November 2018 Warrants for an aggregate of 17,803,031 shares of common stock, at an exercise price of $3.01 per share. Proceeds from the warrant exercise after deducting placement agent fees and other related expenses of $1.1 million were approximately $52.5 million.

The Company issued participating investors new warrants to purchase up to 17,803,031 additional shares of common stock, or the 2019 Warrants, as consideration for the warrant holders to exercise their November 2018 Warrants. The 2019 Warrants will expire on the fifth anniversary of the initial exercise date and have an exercise price of $7.00. The 2019 Warrants were valued using a Black-Scholes valuation model and resulted in a $60.8 million non-cash charge in the Company’s statement of operations in 2019.

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On October 22, 2019, the Company entered into the 2019 R&D Agreement with MD Anderson. In connection with the execution of the 2019 R&D Agreement, the Company issued the MD Anderson Warrant to purchase 3,333,333 shares of common stock. The MD Anderson Warrant has an initial exercise price of $0.001 per share and grant date fair value of $14.5 million. The MD Anderson Warrant expires on December 31, 2026 and vests upon the occurrence of certain clinical milestones. The Company will recognize expense on the MD Anderson Warrant in the same manner as if the Company paid cash for services to be rendered. For the year ended December 31, 2022 and 2021, the Company did not recognize any expense related to the MD Anderson Warrant as the clinical milestones had not been achieved.

On August 6, 2021, the Company entered into the Loan and Security Agreement with SVB. Refer to Note 4, *Debt*. In connection with the Loan and Security Agreement, the Company issued SVB warrants to purchase 432,844 shares of common stock with an exercise price of $2.22 per share. The warrants have a ten-year life and were fully vested upon issuance. The fair value of the warrants was estimated at $0.8 million using a Black-Scholes model with the following assumptions: expected volatility of 79%, risk free interest rate of 1.31%, expected life of ten years and no dividends. On December 28, 2021, the Company entered into the Amended Loan and Security Agreement, as described in Note 4, *Debt,* in connection with which, the original warrants issued to SVB were amended and restated. As amended and restated, the SVB Warrants are for up to 649,615 shares of common stock, in the aggregate, at an exercise price per share of $1.16. The SVB Warrants expire on August 6, 2031 and were fully vested upon issuance. Using a Black-Scholes model with an expected volatility of 81%, risk free interest rate of 1.49%, expected life of 10 years and no dividends, the Company recorded a $0.2 million increase in the fair value of the SVB Warrants due to the modification of the SVB Warrants during the year ended December 31, 2021.

The Company assessed whether the SVB Warrants require accounting as derivatives. The Company determined that the SVB Warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with ASC 815, *Derivatives and Hedging*. As such, the Company has concluded the SVB Warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders' equity.

11. Restructuring

On September 27, 2021, in order to lower its existing cost structure in connection with the realignment of its business strategy, the Company announced a strategic reduction in force and notified approximately 60 full-time employees of its intention to terminate their services on or, in most cases, before November 30, 2021. Certain of the notified employees had employment agreements that provided for enhanced severance benefits. The severance benefits, apart from certain continuing Company-paid health care benefits for up to twelve months, were paid in 2021. The remaining benefits were paid in 2022, which reduced the severance benefits accrual to $0 as of December 31, 2022.

The Company incurred the following costs associated with termination benefit payments resulting from the strategic reduction in force:

($ in thousands)	**December 31, 2021**
Research and development	$ 2,368
General and administrative	1,289
Total severance expense	$ 3,657

12. Income Taxes

There is no provision for income taxes because the Company has incurred operating losses since inception. The reported amounts of income tax expense for the years ended December 31, 2022 and 2021 differ from the amounts that would result from applying domestic federal statutory

tax rates to pretax losses primarily because of the changes in the valuation allowance. Significant components of the Company's deferred tax assets at December 31, 2022 and 2021 are as follows:

	December 31,	
(in thousands)	**2022**	**2021**
Deferred tax assets:		
Net operating loss carryforwards	$ 171,070	$ 164,486
Start-up and pre-clinical studies	17,204	21,705
Research and development credit carryforwards	40,116	39,817
Stock-based compensation	698	706
Capitalized acquisition costs	2,180	2,946
Lease liability	618	1,278
Depreciation	239	102
Capitalized research expenses	5,156	-
Other	27	156
	237,308	231,196
Less valuation allowance	(236,827)	(230,119)
Total deferred tax assets	481	1,077
Right-of-use asset	(481)	(1,077)
Total deferred tax liabilities	$ (481)	$ (1,077)
Net deferred taxes	$ —	$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. At December 31, 2022, the Company has aggregate net operating loss carryforwards for federal tax purposes of approximately $665.5 million, of which approximately $341.7 million expire at various dates through December 31, 2037 and approximately $323.8 million can be carried forward indefinitely. The Company also has approximately $497.9 million of state net operating loss carryforwards available to offset future state taxable income, expiring at various dates through 2042. Additionally, the Company has approximately $40.1 million of federal and state research and development credits at December 31, 2022, expiring in varying amounts through 2042, which may be available to reduce future taxes.

The Company has provided a valuation allowance for the full amount of its net deferred tax assets since it is more likely than not that these future benefits will not be realized. However, these deferred tax assets may be available to offset future income tax liabilities and expenses. The valuation allowance increased by $6.7 million in 2022 due primarily to net operating loss carryforwards and the increase in research and development credits.

Income taxes using the federal statutory income tax rate differ from the Company's effective tax rate primarily due to non-deductible expenses related to the Company's issuance of warrants along with the change in the valuation allowance on deferred tax assets.

A reconciliation of income tax expense (benefit) at the statutory federal income tax rate and income taxes as reflected in the financial statements is as follows:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Federal income tax at statutory rates	21%	21%
State income tax, net of federal tax benefit	3%	3%
Research and development credits	2%	3%
Research and development true-up	-2%	0%
Stock-based compensation	-1%	-1%
Federal/state rate change	-5%	-2%
Change in valuation allowance	-18%	-24%
Effective tax rate	0%	0%

The Company adopted ASC 740, *Accounting for Uncertain Tax Positions* on January 1, 2007. ASC 740 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." ASC 740 prescribes a recognition threshold and measurement of a tax position taken or expected to be taken in a tax return. The

Company did not establish any additional reserves for uncertain tax liabilities upon adoption of ASC 740. There were no adjustments to its uncertain tax positions in the years ended December 31, 2022 and 2021.

The Company has not recognized any interest and penalties in the statements of operations because of the Company's net operating losses and tax credits that are available to be carried forward. When necessary, the Company will account for interest and penalties related to uncertain tax positions as part of its provision for federal and state income taxes. The Company does not expect the amounts of unrecognized benefits will change significantly within the next twelve months.

The Company is currently open to audit under the statute of limitations by the Internal Revenue Service and state jurisdictions for the years ended December 31, 1999 through 2022 to the extent net operating losses continue to be carried forward to 2022.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017, or the Tax Act, eliminated the option to deduct research and development expenditures immediately in the year incurred and requires taxpayers to capitalize and amortize them over five years pursuant to IRC Section 174. The mandatory capitalization requirement had no impact to the overall deferred tax assets due to the Company's loss position and full valuation allowance.

13. Stock Option Plan

The Company adopted the 2012 Equity Incentive Plan, or the 2012 Plan, in May 2012. Including subsequent increases, the Company had reserved 14,000,000 shares for issuance. On December 31, 2022, there were 1,089,296 shares reserved for issuance and no shares available for future grant.

The Company adopted the 2020 Equity Incentive Plan, or the 2020 Plan, in June 2020. The Company reserved 21,000,000 shares for issuance plus a carryover of 1,066,275 shares from the 2012 Plan for a total of 22,066,275 shares. In addition, returning shares from the 2012 Plan are available for issuance under the 2020 Plan. As of December 31, 2022, there were 9,319,326 shares reserved for issuance and 15,460,088 shares available for future grant.

Stock options generally vest ratably in either quarterly or annual installments over three or four years, commencing on the first anniversary of the grant date and have contractual terms of ten years. Stock options to directors generally vest ratably over one or two years and have contractual terms of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation is recognized based on such fair value over the period of vesting on a straight-line basis.

Proceeds from the option exercises during the year ended December 31, 2022 amounted to $21 thousand and during the year ended December 31, 2021 amounted to $1.0 million. The intrinsic value of these options amounted to $26 thousand for the year ended December 31, 2022 and $0.8 million for the year ended December 31, 2021.

Stock option activity under the Company's stock options plans for the years ending December 31, 2022 and 2021 were as follows:

(in thousands, except share and per share data)	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2020	6,840,719	3.81		
Granted	9,380,438	2.62		
Exercised	(363,109)	2.86		
Cancelled	(5,192,179)	3.65		
Outstanding, December 31, 2021	10,665,869	$ 2.87		
Granted	4,697,500	1.08		
Exercised	(26,250)	0.80		
Cancelled	(4,928,497)	3.34		
Outstanding, December 31, 2022	10,408,622	$ 1.84	8.69	$ 3
Options exercisable, December 31, 2022	3,891,598	$ 2.46	8.08	$ —
Options exercisable, December 31, 2021	4,410,312	$ 3.85	7.53	$ —
Options available for future grant, December 31, 2022	15,460,088			

On December 31, 2022, total unrecognized compensation costs related to non-vested stock options outstanding amounted to $6.2 million. The cost is expected to be recognized over a weighted-average period of 1.92 years.

Restricted Stock

For the year ended December 31, 2022 the Company issued 280,000 shares of restricted stock and 1,601,224 in the year ended December 31, 2021 to employees and directors. During the year ended December 31, 2022, the Company repurchased 18,750 shares at a price of $2.41 per share to cover payroll taxes for one employee exercise, which is in accordance with the original terms of the award. There were no repurchases by the Company for the year ended December 31, 2021.

A summary of the status of restricted stock as of December 31, 2022 and 2021 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2020	786,280	3.08
Granted	1,601,224	2.60
Vested	(754,137)	3.40
Cancelled	(434,787)	3.45
Unvested, December 31, 2021	1,198,580	$ 2.10
Granted	280,000	0.82
Vested	(306,617)	2.28
Cancelled	(232,901)	3.15
Unvested, December 31, 2022	939,062	$ 1.40

As of December 31, 2022, there was $1.1 million of total unrecognized stock-based compensation expense related to non-vested restricted stock arrangements. The expense is expected to be recognized over a weighted-average period of 1.78 years.

14. Employee Benefit Plan

The Company sponsors a qualified 401(k) retirement plan under which employees are allowed to contribute certain percentages of their pay, up to the maximum allowed under Section 401(k) of the IRC, or the 401(k) Plan. The Company may make contributions to the 401(k) Plan at its discretion. The Company contributed approximately $0.5 million to the 401(k) Plan during the year ended December 31, 2022 and $0.7 million during the year ended December 31, 2021.

15. Joint Venture

On December 18, 2018, the Company entered into a Framework Agreement with TriArm whereby the parties agreed to launch Eden BioCell to lead clinical development and commercialization of certain *Sleeping Beauty*-generated CAR-T therapies as set forth in a separate license agreement.

On January 3, 2019, Eden BioCell was incorporated in Hong Kong as a private company. Eden BioCell, the Company and TriArm entered into a Share Subscription Agreement on January 23, 2019, where the Company and TriArm agreed to contribute certain intellectual property, services and cash (only with respect to TriArm) to Eden BioCell to subscribe for a certain number of newly issued ordinary shares in the share capital of Eden BioCell.

The closing of the transaction occurred on July 5, 2019. The Framework Agreement and Share Subscription Agreements were each respectively amended to be effective as of this date. Upon consummation of the joint venture, Eden BioCell and the Company also entered into a license agreement, pursuant to which the Company licensed the rights to Eden BioCell for third generation *Sleeping Beauty*-generated CAR-T therapies targeting the CD19 antigen for the territory of China (including Macau and Hong Kong), Taiwan and Korea. TriArm and the Company each received a 50% equity interest in the joint venture in exchange for their contributions to Eden BioCell.

The Company determined that Eden BioCell was considered a variable interest entity, or VIE, and concluded that it is not the primary beneficiary of the VIE as it did not have the power to direct the activities of the VIE. As a result, the Company accounts for the equity interest in Eden BioCell under the equity method of accounting as it has the ability to exercise significant influence.

In March 2021, Eden BioCell began treating patients in a clinical trial with the Company's investigational CD19 RPM CAR-T cell therapy, under the IND cleared by the Taiwan FDA in December 2020. In the first half of 2021, two patients were treated in this trial. The lead investigator at National Taiwan University in Taipei, has reported no serious adverse safety events in either of these patients. Laboratory results continue to support, as previously published, that non-viral *Sleeping Beauty* gene transfer is effective in genetically modifying autologous T-cells. Patients were infused two days after gene transfer, thus shortening the turnaround time and demonstrating an advantage over viral methods.

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Based on laboratory data from the first two patients generated between March and May 2021, the TriArm/Eden team concluded, in concert with the investigator and the Company, that further process development work is required.

For the years ended December 31, 2022 and 2021, Eden BioCell incurred a net loss. In September 2021, TriArm and the Company mutually agreed to dissolve the joint venture, which has now been terminated. The Eden BioCell entity is in the process of being dissolved.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Nos. 333-129884, 333-134280, 333-142701, 333-160496, 333-167925, 333-185433, 333-199304, 333-220804, 333-228291, 333-238090, 333-241698 and 333-263983) on Form S-8 and Registration Statements (Nos. 333-134279, 333-141014, 333-161453, 333-162160, 333-163517, 333-166444, 333-174292, 333-177793, 333-201826, 333-229555, 333-232283 and 333-266841) on Form S-3 of Alaunos Therapeutics, Inc. of our report dated March 7, 2023, relating to the financial statements of Alaunos Therapeutics Inc. and subsidiaries, appearing in this Annual Report on Form 10-K of Alaunos Therapeutics, Inc. for the year ended December 31, 2022.

/s/ RSM US LLP

Boston, Massachusetts
March 7, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

I, Kevin S. Boyle, Sr., certify that:

1) I have reviewed this Annual Report on Form 10-K of Alaunos Therapeutics, Inc.;
2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2023

/s/ Kevin S. Boyle, Sr.

Kevin S. Boyle, Sr.
Chief Executive Officer and Director
Principal Executive Officer and
Principal Financial Officer

Exhibit 32.1

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

In connection with the Annual Report of Alaunos Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin S. Boyle, Sr., Principal Executive Officer and Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

/s/ Kevin S. Boyle, Sr.
Kevin S. Boyle, Sr.
Chief Executive Officer and Director
Principal Executive Officer and
Principal Financial Officer
March 7, 2023