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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, 2021

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. ☐

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 $543,706,424 as of June 30, 2021 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 205,949,403 shares of common stock held by non-affiliates and a closing price of $2.64 as reported on the Nasdaq Global Select on June 30, 2021. 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 21, 2022, there were 216,127,443 shares of the registrant's common stock, $0.001 par value per share, outstanding.

Alaunos Therapeutics, Inc.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2021

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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 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 preclinical studies, clinical trials and research and development 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 liability (formerly deferred revenue), 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;
- our expectations regarding the impact of the COVID-19 pandemic, including the expected duration of disruption to key clinical trial activities, limitations on travel, quarantine and social distancing protocols, diversion of healthcare resources away from the conduct of or clinical trials, and other immediate and long-term impact and effect on our business and operations.

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," "our," "Ziopharm Oncology, Inc.," or "Ziopharm" 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 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, if we fail to achieve certain clinical milestones or equity raise requirements we will be 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 trials, which are 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 cell-based and gene 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.
- 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.
- We previously identified a material weakness in our internal control over financial reporting for the quarter ended June 30, 2021, which we believe has been fully remediated. If we have inadequately remediated this material weakness, or we otherwise fail to develop, implement and maintain an effective system of internal controls in future periods, our ability to report our financial condition or results of operations could be adversely affected and 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.
- 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 clinical research organizations, or CROs, shippers and others.

PART I

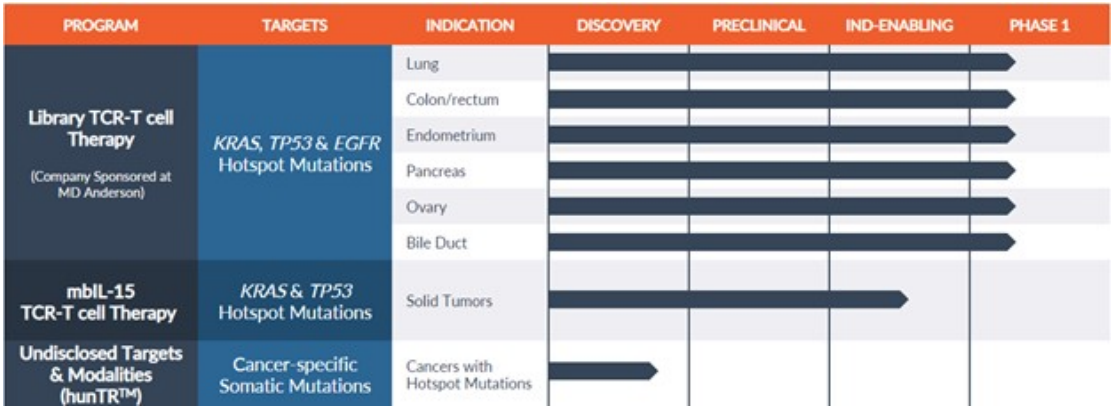
Item 1. Business

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 novel cancer mutation hotspot TCR library and our proprietary, non-viral *Sleeping Beauty* genetic engineering technology 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 ten 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. We anticipate treating our first patient in this trial in the second quarter of 2022 and reporting interim data in the second half of 2022.

In the United States, solid tumors represent approximately 90% of new cancer diagnoses. Approximately 1.9 million people are expected to be diagnosed with cancer in the United States in 2022 and approximately 609,000 people are expected to die from cancer in the United States in 2022. 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 2022. In 2022, it is estimated that 236,740 people will be diagnosed with lung and bronchus cancer, 151,030 will be diagnosed with colorectal cancer, 65,950 people will be diagnosed with endometrial cancer, 62,210 people will be diagnosed with pancreatic cancer, 19,880 people will be diagnosed with ovarian cancer and approximately 7,400 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 ten TCRs targeting six solid tumor indications.
- *Sleeping Beauty Genetic Engineering Technology*: 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 and killer 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 only 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 there is no further genetic engineering employed.

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 CARs, which directly recognize antigens, such as CD19, such as on the surface of malignant B cells, without the need for 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 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

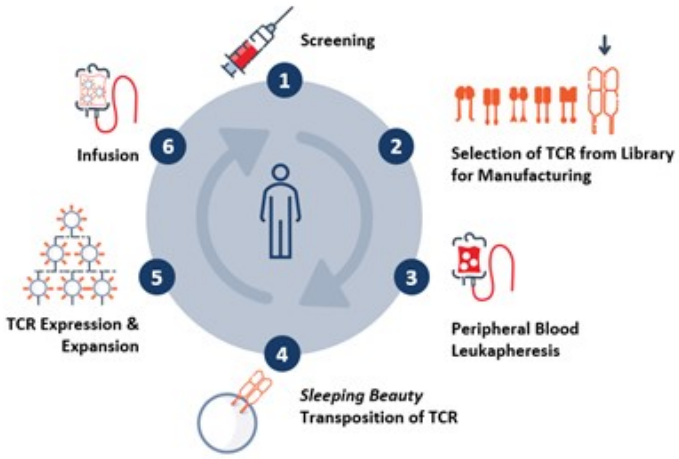
We believe that to be successful in treating solid tumors, genetically modified T cells targeting one or more neoantigens will likely need to address the fact that (1) among a population of patients, not all tumors express the targeted neoantigen, referred to as inter-tumor heterogeneity, and (2) within 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 Process

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



Our Library 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 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 the product phenotype, 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, transferred to the hospital facility, and infused in the patient.

Benefits of Our Sleeping Beauty Genetic Engineering Technology

Our *Sleeping Beauty* genetic engineering technology 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 the 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 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.
- *Potential Clinical Benefits*. We believe the anti-tumor immune response generated by 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 regression in patients. In CAR-T cell products generated in human cells, *Sleeping Beauty* transposons have been 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 an ability to persist longer after infusion.

- *Technology can accommodate large transgene size*. Plasmids manufactured using our *Sleeping Beauty* technology have a sufficiently large payload size which allows for genetic engineering of both the TCR as well as insertion of a gene encoding for the expression of cytokines, including IL-15. This facilitates uniformly high co-expression of both the TCR and cytokine on a single integrated gene.

Pre-Clinical and Clinical Development

Pre-clinical Development of our TCR-T Product Candidates

We have independently evaluated all licensed TCRs using our *Sleeping Beauty* technology. Candidate TCRs for clinical translation were selected based on conventional *in vitro* immunological measurements. We have 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 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 pre-clinical data suggested that TCR-T cells can kill the appropriate tumor cell lines expressing the target neoantigen. In our pre-clinical 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 library 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 the 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. 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 this technology and are working towards presenting preclinical data from this program at a major scientific conference in 2022 and filing a related Investigational New Drug Application, or IND, in 2023.

TCR-T Library Phase 1/2 Clinical 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. 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 will evaluate our ten 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 anticipate using our hunTR discovery engine to add new TCRs to our library and clinical program as they are qualified by our laboratory. The patients will be enrolled in cohorts according to their cancer and 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 to determine the objective response rate and otherwise evaluate safety and tolerability. We are also monitoring TCR-T cell persistence and multiple conventional immune monitoring assays in the clinical trial to evaluate this phenomenon in patients. We expect to dose the first patient in the second quarter of 2022 and to provide an interim data update in the second half of 2022.

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

In an effort to control costs, and given our internal expertise, we made the strategic decision to focus the manufacturing of our TCR-T cell product candidates in our own facility rather than utilize a third-party contract manufacturer. During 2021, we completed the construction, commissioning and validation of our cGMP facility in Houston, Texas. The facility 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 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, 2021, we have four 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. As between us and PGEN, the terms of the License Agreement replace and supersede the terms of: (a) that certain Exclusive Channel Partner Agreement by and between us and Precigen, dated January 6, 2011, as amended by the First Amendment to Exclusive Channel Partner Agreement effective September 13, 2011, the Second Amendment to the Exclusive Channel Partner Agreement effective March 27, 2015, and the Third Amendment to Exclusive Channel Partner Agreement effective June 29, 2016, which was subsequently assigned by Precigen to PGEN; (b) certain rights and obligations pursuant to that certain License and Collaboration Agreement effective March 27, 2015 between us, Precigen and ARES TRADING S.A., or Ares Trading, a subsidiary of Merck KGaA, or Merck, as assigned by Precigen to PGEN, or the Ares Trading Agreement; (c) that certain License Agreement between us, Precigen, and MD Anderson, with an effective date of January 13, 2015, or the MD Anderson License, which was subsequently assigned by Precigen and assumed by PGEN effective as of January 1, 2018; and (d) that certain research and development agreement between us, Precigen and MD Anderson with an effective date of August 17, 2015, or the 2015 R&D Agreement, and any amendments or statements of work thereto.

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 Ares Trading Agreement. 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 will pay PGEN an annual license fee of $100,000 and we have agreed to reimburse PGEN for certain historical costs of the licensed programs up to $1.0 million, which was fully paid during the year ending December 31, 2019.

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 twenty percent 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 consideration of our entry into the License Agreement, PGEN forfeited and returned to us all shares of our Series 1 preferred stock. The transaction represented a capital transaction between related parties and the settlement was accounted for during the year ended December 31, 2018.

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 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 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 (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.

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.

In connection with the execution of the 2019 R&D Agreement described below, on October 22, 2019, we 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 R&D Agreement.

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

On October 22, 2019, we entered into the 2019 Research and Development Agreement, or the 2019 R&D Agreement, with MD Anderson pursuant to which the parties agreed to collaborate with respect to the TCR program. Under the 2019 R&D Agreement, the parties 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 intellectual property 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 outside the field of oncology and to develop and commercialize TCR products manufactured using viral gene transfer technologies, and a non-exclusive license for 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. For the year ended December 31, 2021, we incurred expenses of $0.5 million related to this agreement.

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 upon the occurrence of certain clinical milestones. As of December 31, 2021, none of the milestones have 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.

Pursuant to the terms of the Patent License, we are required to pay the NCI a cash payment in the aggregate amount of $1.5 million payable in $0.5 million installments within sixty days, six-months, and the twelve-month anniversary of the effective date of the agreement for the Patent License. We also reimbursed the NCI for past patent expenses in the aggregate amount of approximately $46,000. Under the amendment to the patent license signed in January 2020, we agreed to pay the NCI a cash payment of $600,000 within sixty days of the amendment and under the amendment to the patent license signed in September 2020, we agreed to pay the NCI a cash payment of $411,000 within sixty days of the amendment.

The terms of the Patent License also 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 will be due upon the initiation of our first sponsored Phase 1 clinical trial of a licensed product or licensed process in the field of use licensed under 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, 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 and PGEN researchers.

We are responsible for providing 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 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 due to matters internal to the NCI and unrelated to our technology. 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. During the year ended December 31, 2020, we made payments of $2.5 million and during the year ended December 31, 2021, we paid $1.25 million, pursuant to the CRADA. For the third and fourth quarters of 2021, we were not required to make payments towards the program as agreed with the NCI. 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.

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 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 current Good Manufacturing Practices, or 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 which 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 physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous 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, the ACA was enacted, which includes measures that have significantly changed healthcare financing by both governmental and private insurers. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- created an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drug agents or biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;
- created 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;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- created a new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians;

- expanded healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- created new requirements under the federal Physician Payments Sunshine Act for drug manufacturers to annually report information related to payments and other transfers of value made to physicians and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members;
- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow on biologic products.

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." On December 14, 2018, a Texas U.S. District Court Judge ruled that ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the United States Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

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 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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 20, 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 implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. 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 pending review by the Biden administration until

March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

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 of the 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 Achilles Therapeutics, Adaptimmune Therapeutics in collaboration with GlaxoSmithKline, Affini-T Therapeutics, ArsenalBio, bluebird bio, BioNTech, Bristol-Myers Squibb, Immatics, Iovance Biotherapeutics, Lion TCR, Lyell Immunopharma, Medigene, Nurix Therapeutics, Neogene Therapeutics, NexImmune, PACT Pharma, Precigen, Tactiva Therapeutics, Takara Bio, TCR2 Therapeutics, T-knife Therapeutics, Tmunity Therapeutics, 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 (TIL). 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 Therapeutics, Affini-T Therapeutics, Immatics, Enara Bio, T-knife Therapeutic, TScan Therapeutics and 3T Biosciences. Several companies, including Advaxis, Amgen, BioNTech, Geneos Therapeutics, and Gritstone Oncology, 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 Crispr Therapeutics.

Several companies are pursuing the development of allogeneic CAR-T therapies, including Allogene Therapeutics, Atara Biotherapeutics, Precision Biosciences, and Servier (in collaboration with Cellectis) 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 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 cell-based treatments offered by other companies such as Amgen, AstraZeneca, Bristol-Myers Squibb, Incyte, Merck, and Roche.

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 March 15, 2022, we had 41 full-time employees and no part-time employees, 33 of whom were engaged in research and development activities, and 8 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 8080 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 very 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. The impact of COVID-19 may also exacerbate other risks discussed in this filing, any of which could have a material effect on us. This situation is changing rapidly and additional impacts may arise. 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 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, 2021, we had a net loss of $78.8 million, and, as of December 31, 2021, our accumulated deficit since inception in 2003 was $842.9 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, 2021, we have approximately $76.1 million of cash and cash equivalents. Given our current development plans and cash management efforts, we anticipate cash resources will be sufficient to fund operations into the second quarter of 2023, 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 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. The COVID-19 pandemic continues to evolve and has 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, 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 with Silicon Valley Bank, or SVB, and affiliates of SVB, or 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, or the SVB Facility. In connection with the initial borrowing, we also issued warrants to SVB and certain of its affiliates 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, 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 amendment to the 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.

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. Furthermore, the ongoing impact of COVID-19 and geopolitical instability, including the recent military conflict between Russian and Ukraine, on global financial markets could make the terms of any available financing less attractive to use and more dilutive to our existing shareholders. 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 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, a failure to comply with certain equity raise and clinical milestone requirements in the amended Loan and Security Agreement could result in us having 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. 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 identified a material weakness in our internal control as of June 30, 2021, which has been remediated as of December 31, 2021. 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, the Sarbanes-Oxley Act of 2002 and the rules and regulations of the Nasdaq Global Select Market. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, 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.

In connection with the review of our financial statements as of and for the quarter ended June 30, 2021, we identified a material weakness in our internal control over financial reporting. 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. Our identified material weakness existing in our financial reporting process relates to the lack of sufficient accounting resources to execute certain controls related to the reconciliation and review of accounts in a timely manner.

Following the identification of the material weakness in our internal controls over financial reporting as of June 30, 2021, we prepared a remediation action plan and implemented that plan to improve the controls related to the reconciliation and review of accounts in a timely manner. We enhanced and revised the design of related existing internal controls, implemented incremental controls over our financial statement close process and hired new accounting staff. During the fourth quarter of 2021, we successfully completed the testing necessary to conclude that the material weakness has been remediated. The material weakness had no impact on any amounts reported in the financial statement for the fiscal year ended December 31, 2021 or for any previous period.

Although the material weakness has 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. We also previously had a material weakness identified for the year ended December 31, 2019, which was fully remediated as of December 31, 2020. 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 intend to employ 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 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 the patient or third parties that can be administered to a 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 delivering each of the potential products, which may increase the risk of adverse side effects 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, all of which has been generated through trials conducted by MD Anderson and the NCI, not 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 determine to advance could negatively affect the timing of our potential future clinical trials. Such an impact on timing could increase research and 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 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, which 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. We do not know at this stage whether patient response data from 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 solid tumors and plan to develop product candidates for use in 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 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.

In 2021, we experienced transitions in our senior management culminating in the appointment of Kevin S. Boyle, Sr. as Chief Executive Officer and a member of the board of directors in August 2021 and the hiring of Michael Wong as our Vice President, Finance in September 2021 and his appointment as principal accounting officer in November 2021. In November 2021, we hired Melinda Lackey as our Senior Vice President, Legal. Management transition is often difficult and inherently causes some loss of institutional knowledge and creates potential uncertainty in strategy execution.

In addition, we may not be able to attract or retain qualified management and commercial, scientific 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 Achilles Therapeutics, Adaptimmune Therapeutics in collaboration with GlaxoSmithKline, Affini-T Therapeutics, ArsenalBio, bluebird bio, BioNTech, Bristol-Myers Squibb, Immatics, Iovance Biotherapeutics, Lion TCR, Lyell Immunopharma, Medigene, Nurix Therapeutics, Neogene Therapeutics, NexImmune, PACT Pharma, Precigen, Tactiva Therapeutics, Takara Bio, TCR^2 Therapeutics, T-knife Therapeutics, Tmunity Therapeutics, 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 Therapeutics, Affini-T Therapeutics, Immatics, Enara Bio, T-knife Therapeutics, TScan Therapeutics and 3T Biosciences. Several companies, including Advaxis, Amgen, BioNTech, Geneos Therapeutics, and Gritstone Oncology, 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 Crispr Therapeutics.

Several companies are pursuing the development of allogeneic CAR-T therapies, including Allogene Therapeutics, Atara Biotherapeutics, Precision Biosciences, and Servier (in collaboration with Cellectis), 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, 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- cell-based treatments offered by other companies such as Amgen, AstraZeneca, Bristol-Myers Squibb, Incyte, Merck, and Roche. Additionally, our ability to pursue 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 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 our patent license agreement 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 Clinical 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, by failing to meet the defined milestones by the required dates, or upon certain insolvency events that are not cured within the 90-day time limit once we are notified of such alleged breach. 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 and March 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. Further, in response to the COVID-19 pandemic, the NCI has taken precautionary measures that have delayed the enrollment of the personalized TCR-T clinical trial using the *Sleeping Beauty* system to express TCRs for the treatment of solid tumors. In addition, enrollment in this clinical trial has been temporarily suspended due to issues internal to NCI and unrelated to our technology. 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.

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. Competition for qualified individuals is intense among numerous biopharmaceutical companies, universities, and other research institutions and we cannot be certain that our search will be successful. If we are unable to manage our growth effectively, including attracting and retaining qualified personnel, our business may be harmed.

Restructuring activities could disrupt our business and effect our results of operations. In addition, we may not achieve anticipated benefits and saving from such restructuring activities.

In September 2021, we announced a restructuring enabling us to focus on and enhance our TCR program. We eliminated approximately 60 positions, representing more than 50% of our workforce. The restructuring resulted in the loss of institutional knowledge and expertise and the reallocation of and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Further, the restructuring and possible additional cost-containment measures may yield unintended consequences, such as attrition beyond our intended workforce reduction and reduced employee morale. In addition, we may not achieve anticipated benefits from the restructuring. Due to our limited resources, we may not be able to effectively manage our operations or retain qualified personnel, which may result in weaknesses to our infrastructure and operations, risks that we may be unable to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, manufacturing and regulatory functions, which would have a negative impact on our ability to successfully develop and, ultimately, commercialize our product candidates. If our management is unable to successfully manage this transition and restructuring activities, our expenses may be more than expected and we may be unable to implement our business strategy. As a result, our future financial performance and our ability to commercialize our product candidates successfully would be negatively affected.

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.

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.

The global COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar epidemic is highly uncertain and subject to change. We may experience a material impact on our operations, and we continue to monitor the COVID-19 situation closely.

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 may experience difficulties in patient enrollment in our clinical trials, including our ongoing TCR-T Library Phase 1/2 Trial, 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 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; 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 some of our clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment.

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

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, 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 approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, 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. 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, 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 was 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 products 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 cell-based 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 will require 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 the DNA plasmids used, 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 many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, 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, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

In addition, some of the reagents and products used by us, including in our clinical trials, 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. We recently began manufacturing our product candidates at our in-house 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. While 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.

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 will be subject to review and oversight by the FDA upon commencement of the manufacturing of our product candidates for our TCR-T Library Phase 1/2 Trial. We will be subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with current good manufacturing practices, or cGMP, and other government regulations. Our license to manufacture product candidates will be 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 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.

In addition, it is possible that we could experience manufacturing difficulties in the future due to resource constraints or because of labor disputes. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients could be materially adversely affected.

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 development work came from healthy donors. Once we have experience with working 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 trials, and if our 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 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 products, 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 and clinical testing 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 countries; 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 products 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 requires 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 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 products 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, which included measures that have significantly changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of importance to the pharmaceutical industry are the following:

- Created an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- Increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- Created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- Extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- Created new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extensions;
- Expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- Expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- Created a new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians;
- Expanded healthcare fraud and abuse laws, including the False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- Created a licensure framework for follow-on biologic products;
- Created new requirements under the federal Physician Payments Sunshine Act for certain drug manufacturers to annually report information related to payments and other transfers of value made to physicians, as defined by such law, and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members;
- Created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- Established a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug 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 Cuts and Jobs Act of 2017, or the Tax Act. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued that ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a

special enrollment period for purposes of obtaining health care coverage through the ACA marketplace, which began on February 21, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is 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 20, 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 implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. 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 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation, challenging the MFN model on August 10, 2021, CMS published a proposed rule that seeks to rescind the MFN model interim rule. 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. 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.

It is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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 and applicable group purchasing organizations during the preceding calendar year, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding its payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous 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 our consulting agreements with physicians, some of whom 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 contract research organizations 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. In addition, due to the COVID-19 pandemic, we have enabled many of our employees to work remotely, which may make us more vulnerable to cyberattacks. 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 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 agreement 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 followed. Under the patent license agreement 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 agreement, 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 followed. 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 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, MD Anderson, 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, 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, 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 our MD Anderson License, our license agreement with the NCI, and our license agreement with PGEN. 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 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 the COVID-19 pandemic;
- 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.

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.

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 March 17, 2022, 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 September 13, 2022, 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 would anticipate reviewing our options to regain compliance with the minimum bid requirements, including conducting a reverse stock split. On March 21, 2022, the closing price of our common stock was $0.73 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 Markets 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 we are 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 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 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 such 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, 2021, we had 22,922,342 warrants 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 2012 Equity Incentive Plan, or the 2020 Equity Incentive Plan. Under the 2020 Equity Incentive Plan, 7,818,679 shares were issuable upon the exercise of outstanding options at a weighted average exercise price of $2.46 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, 2021, our executive officers, directors and holders of five percent or more of our outstanding common stock beneficially owned, in the aggregate, 41.6% 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 if our annual revenues are $100 million or more, or until our public float exceeds $700 million if our annual revenues are less than $100 million.

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 32,148 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 but are seeking an acceptable sublessee 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. See Note 8 to the accompanying financial statements 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 March 15, 2022, we had approximately 246 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

Except as previously disclosed in Current Reports on Form 8-K (File No. 001-33038) that we filed with the SEC on August 12, 2021 and January 4, 2022, we did not sell or issue any equity securities during the twelve months ended December 31, 2021 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, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. We are leveraging our novel cancer mutation hotspot 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 MD Anderson, we are currently enrolling patients for a Phase 1/2 clinical trial evaluating ten 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, which we refer to as our TCR-T Library Phase 1/2 Trial. We anticipate treating our first patient in this trial in the second quarter of 2022 and reporting interim data in the second half of 2022.

As of December 31, 2021, we have approximately $76.1 million of cash and cash equivalents. Given our current development plans, we anticipate our cash resources will be sufficient to fund our operations into the second quarter of 2023, and we have no committed sources of additional capital at this time. See "Liquidity and Capital Resources."

Our amended and restated certificate of incorporation authorizes us to issue 350,000,000 shares of common stock. As of December 31, 2021, there were 216,127,443 shares of common stock outstanding and an additional 33,620,711 shares of common stock reserved for issuance pursuant to outstanding stock options and warrants. We may need additional shares for business and financial purposes in the future.

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, 2021, we had a net loss of $78.8 million, and through December 31, 2021, we have incurred approximately $842.9 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.

Recent Developments

On September 27, 2021, we announced a restructuring designed to enable us to focus on and advance our TCR program. As a result of the restructuring, approximately 60 positions were eliminated, and we anticipate that the cost savings associated with the restructuring will extend our cash runway. Given our current development plans and cash management efforts, we anticipate cash resources will be sufficient to fund operations into the second quarter of 2023.

The ongoing COVID-19 global pandemic has presented a significant health and economic challenge around the world and may affect our employees, partners and business operations. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted. Supply chain disruptions caused by the pandemic may negatively impact productivity, disrupt our business and delay our clinical programs and timelines. The severity of negative impacts will depend, in part, on the length and magnitude of the disruptions. These and perhaps more severe

disruptions in our operations could negatively impact our business, operating results and financial condition. We continue to work with our partners to mitigate the impact the COVID-19 pandemic is having on our business.

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.

We have not accumulated and tracked our internal historical research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources are allocated across several projects, and many of our costs are directed to broadly applicable research endeavors. As a result, we cannot state the costs incurred for each of our oncology programs on a program-by-program basis.

We do track our accumulated costs by program for costs incurred by outside vendors conducting research for our named clinical candidates. For the year ended December 31, 2021, our clinical stage projects included our TCR-T Library Phase 1/2 Trial evaluating TCRs from our library for the investigational treatment of non-small cell lung, colorectal, endometrial, pancreatic, ovarian, and bile duct cancers; a Phase 2 clinical trial of Ad-RTS-hIL-12 with veledimex in combination with cemiplimab-rwlc in progressive glioblastoma; a Phase 1/2 clinical trial of Ad-RTS-hIL-12 with veledimex for the treatment of pediatric brain tumors; a Phase 1 clinical trial with Ad-RTS-IL-12 plus veledimex in progressive glioblastoma; and a Phase 1 clinical trial infusing our second generation CD19-specific CAR-T cells in patients with advanced lymphoid malignancies. Since December 31, 2021, we have significantly reduced spending on all programs other than our TCR-T Library Phase 1/2 Trial. Costs incurred by outside vendors conducting research for our named clinical candidates during the year ended December 31, 2021 and through inception are as follows:

(in millions)	Year ended December 31, 2021	Since Inception, Through December 31, 2021
Direct external expenses by program:		
TCR-T Library Phase 1/2 Trial	$ 15.4	$ 15.4
Ad-RTS-hIL-12 with veledimex in combination with cemiplimab-rwlc	$ 1.5	$ 7.9
Ad-RTS-hIL-12 with veledimex for the treatment of pediatric brain tumors	$ 0.2	$ 2.7
Ad-RTS-IL-12 plus veledimex in progressive glioblastoma	$ 0.3	$ 14.9
CD19-specific CAR+ T cells in patients with advanced lymphoid malignancies	$ 0.1	$ 6.2

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 Loan and Security Agreement.

Results of Operations for the Fiscal Years ended December 31, 2021 and 2020

	For the Year Ended December 31,	
	2021	2020
Collaboration revenue	$ 398	$ —
Operating expenses:		
Research and development	49,643	52,696
General and administrative	27,564	27,665
Property and equipment and right-of-use assets impairment	740	-
Total operating expenses	77,947	80,361
Loss from operations	(77,549)	(80,361)
Other income (expense), net	(1,202)	385
Net loss	$ (78,751)	$ (79,976)
Net loss applicable to common stockholders	$ (78,751)	$ (79,976)

Collaboration Revenue

Collaboration revenue during the years ended December 31, 2021 and 2020 were as follows:

	Year ended December 31,		Change	
($ in thousands)	2021	2020		
Collaboration revenue	$ 398	$ —	$ 398	100%

Collaboration revenue during the year ended December 31, 2021 was $0.4 million compared to $0 during the year ended December 31, 2020. The increase was due to $0.4 million we recognized in the current year from a collaboration agreement.

Research and Development Expenses

Research and development expenses during the years ended December 31, 2021 and 2020 were as follows:

	Year ended December 31,		Change	
($ in thousands)	2021	2020		
Research and development	$ 49,643	$ 52,696	$ (3,053)	(6)%

Research and development expenses for the year ended December 31, 2021 decreased by $3.1 million, or 6%, when compared to the year ended December 31, 2020 primarily due to a decrease in program-related costs of $9.2 million as a result of the winding down of our IL-12 and CAR-T programs. The decrease was partially offset by an increase of $4.3 million in employee related expenses, including a $2.2 million

severance charge related to our strategic restructuring event in the third quarter of 2021, and a $1.8 million increase in facilities and other related expenses primarily related to our expanded facilities in Houston.

General and Administrative Expenses

General and administrative expenses during the years ended December 31, 2021 and 2020 were as follows:

	Year ended December 31,		Change	
($ in thousands)	**2021**	**2020**		
General and administrative	$ 27,564	$ 27,665	$ (101)	(0)%

General and administrative expenses for the year ended December 31, 2021 decreased by $0.1 million as compared to the year ended December 31, 2020, primarily due to a decrease in professional services of $4.4 million, partially offset by a $4.3 million increase in employee related expenses, including a $1.3 million severance charge related to our strategic restructuring event in the third quarter of 2021 and other severance-related charges incurred during 2021.

Impairments

Impairments during the years ended December 31, 2021 and 2020 were as follows:

	Year ended December 31,		Change	
($ in thousands)	**2021**	**2020**		
Property and equipment and right-of-use assets impairment	$ 740	$ —	$ 740	100%

Impairments during the year ended December 31, 2021 were $0.7 million compared to $0 during the year ended December 31, 2020. The increase was due to a change in the intended use of our Boston office, resulting in 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.

Other Income (Expense)

Other income (expense) during the years ended December 31, 2021 and 2020 was as follows:

	Year ended December 31,		Change	
($ in thousands)	**2021**	**2020**		
Interest expense, net	$ (1,182)	$ -	$ (1,182)	(100)%
Other income (expense), net	(20)	385	(405)	(105)%
Total	$ (1,202)	$ 385	$ (1,587)	(412)%

Total other income (expense), net for the year ended December 31, 2021 increased by $1.6 million as compared to the year ended December 31, 2020 due to $1.2 million of interest expense associated with our Loan and Security Agreement, as defined below, and a reduction in other income of $0.4 million.

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, 2021, we have received an aggregate of $714.1 million from issuances of equity and $25.0 million from our Loan and Security Agreement, as defined below.

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. On December 28, 2021, we entered into a First Amendment, or the Amendment, to the 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 $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 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 provides for an interest-only period which extends through August 31, 2022, as compared to March 31, 2022 in the Loan and Security Agreement, and may be automatically extended through August 31, 2023, if, on or prior to August 31, 2022, SVB receives evidence, satisfactory to it, confirming that we have (i) received at least $50.0 million in net cash proceeds from the sale of our equity securities after the date of the Amended Loan and Security Agreement, on terms and conditions acceptable to SVB, and (ii) achieved positive data in the first cohort of the TCR-T Library Phase 1/2 Trial endorsed by an independent safety monitoring committee as a safe dose to proceed (together, the "Amended Milestones"). After the interest-only payment period, aggregate outstanding borrowings are repayable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding principal and accrued and unpaid interest under the SVB Facility and all other outstanding obligations under the Amended Loan and Security Agreement are due and payable on August 1, 2023; however, if we achieve the Amended Milestones on or prior to August 31, 2022, then the maturity will be automatically extended to August 1, 2024. In addition to the payment of the outstanding principal plus accrued interest due, we will also owe SVB a final payment fee equal to 5.75% of the original principal amounts borrowed. We are permitted to make up to two prepayments, each payment of at least $5.0 million, subject to the prepayment premium of the SVB Facility. Such prepayment premium would be 3.00% of the principal amount of the SVB Facility if prepaid prior to the first anniversary of the effective date, 2.00% of the principal amount of the SVB Facility if prepaid on or after the first anniversary of the effective date but prior to the second anniversary of the effective date and 1.00% of the principal amount of the SVB Facility if prepaid on or after the second anniversary of the effective date but prior to maturity date. No amount that has been repaid may be reborrowed.

The Loan and Security Agreement required us to cash collateralize half of the sum of the outstanding principal amount of the term loans, plus an amount equal to 5.75% of the original principal amount of any portion of the SVB Facility actually extended, if we failed to achieve to a certain fundraising milestone on or prior to December 31, 2021. The Amended Loan and Security Agreement revised our cash collateralization obligation to require us to cash collateralize half of the sum of only 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 if we do not achieve the Amended Milestones on or prior to August 31, 2022. In the event a cash collateralization were to occur, so long as no event of default has occurred and, after subtracting the eighth scheduled payment of principal and interest on the SVB Facility, the sum of the aggregate of outstanding principal and accrued and unpaid interest, plus the final payment, is equal to or less than $9,770,933, then, within ten business days of the date of receipt of the eighth scheduled payment of principal and interest on the SVB Facility, SVB will release $2.5 million from the collateral account, so long as the balance in the collateral account after the release would equal or exceed $10.0 million. If no event of default has occurred and, after subtracting the tenth scheduled payment of principal and interest on the SVB Facility, the sum of the aggregate of outstanding principal and accrued and unpaid interest, plus the final payment, is equal to or less than $5,604,167, then, within ten business days of the date of receipt of the tenth scheduled payment of principal and interest on the SVB Facility, SVB will release a further $4.0 million from the collateral account, so long as the balance in the collateral account after the release would equal or exceed $6.0 million. 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, par value $0.001 per share, in the aggregate, and (ii) up to an additional 432,842 shares of Common Stock, in the aggregate, in the event we achieve certain clinical milestones, in each case at an exercise price per share of $2.22. In connection with the entry into the Amendment, 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.

February 2020 Public Offering

On February 5, 2020, we issued and sold 27,826,086 shares of our common stock at an offering price to the public of $3.25 per share, for aggregate net proceeds of approximately $84.8 million after deducting underwriting discounts and offering expenses paid by us. The offering was made pursuant to our effective registration statement on Form S-3ASR (File No. 333-232283) previously filed with the SEC, and a prospectus supplement thereunder.

On March 10, 2020, the underwriters exercised their option to purchase an additional 1,284,025 shares. The net proceeds were approximately $3.9 million after deducting underwriting discounts and offering expenses paid by us.

At-the-Market Facility

In June 2019, we entered into an Open Market Sale Agreement, or Sales Agreement, with Jefferies LLC as a sale agent pursuant to which we may offer and sell, from time to time through Jefferies, shares of our common stock having an aggregate offering value of up to $100.0 million. Shares will be sold pursuant to our effective registration statement on Form S-3ASR (File No. 333-232283), as previously filed with the SEC. Subject to the terms of the Sales Agreement, we are able to determine, at our sole discretion, the timing and number of shares to be sold under this at-the-market, or ATM, facility. The compensation to Jefferies for sales of our common stock pursuant to the Sales Agreement will be an amount equal to 3% of the gross proceeds of any shares of common stock sold under the sales agreement. During the year ended December 31, 2020, we issued and sold an aggregate of 2,814,673 shares for aggregate net proceeds of approximately $13.0 million after deducting underwriting discounts and offering expenses payable by us. We did not sell any shares of our common stock under the ATM facility during the year ended December 31, 2021.

Cash Flows

The following table summarizes our net increase (decrease) in cash and cash equivalents for the years ended December 31, 2021 and 2020:

	Year ended December 31,	
	2021	2020
($ in thousands)		
Net cash provided by (used in):		
Operating activities	$ (61,468)	$ (57,013)
Investing activities	(3,323)	(9,778)
Financing activities	25,776	102,119
Net increase (decrease) in cash and cash equivalents	$ (39,015)	$ 35,328

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 amortization, stock-based compensation, inducement warrant expense, and warrants for common stock issued; 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, 2021 was $61.5 million, as compared to $57.0 million for the year ended December 31, 2020. 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 $9.2 million, and an increase in accounts payable of $0.3 million. The net cash used in operating activities for the year ended December 31, 2020 was primarily a result of our net loss of $80.0 million, an increase in receivables of $1.3 million, an increase in other noncurrent assets of $0.6 million, partially offset by a decrease in prepaid expenses and other current assets of $11.6 million primarily related to the use of funds at MD Anderson and an increase in accounts payable and accrued expenses of $5.3 million.

Net cash used in investing activities was $3.3 million for the year ended December 31, 2021 as compared to $9.8 million for the year ended December 31, 2020. The $6.5 million decrease in net cash used in investing activities for the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily a result of the decision to use available cash to expand our internal cell therapy capabilities in our Houston, Texas facilities during 2020.

Net cash provided by financing activities was $25.8 million for the year ended December 31, 2021 compared to $102.1 million for the year ended December 31, 2020. The $25.8 million provided by financing activities during 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. Net cash provided by financing activities was $102.1 million for the year ended December 31, 2020, was primarily a result of net proceeds of $88.7 million from the issuance of common stock in our follow-on public offering and $13.0 million from the issuance of common stock under our ATM facility.

Operating Capital and Capital Expenditure Requirements

We anticipate that losses will continue for the foreseeable future. As of December 31, 2021, our accumulated deficit was approximately $842.9 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, 2021, we had approximately $76.1 million of cash and cash equivalents. Given our current development plans, we anticipate our cash resources will be sufficient to fund our operations into the second 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 as of December 31, 2021 was $62.8 million, consisting of $78.8 million in current assets and $16.0 million in current liabilities. Working capital as of December 31, 2020 was $112.2 million, consisting of $130.6 million in current assets and $18.4 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 lease for a portion of office space currently held at our office in Boston. The renewal of the portion of our office space was originally set to expire on August 31, 2021 but was extended 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. Refer to Note 8, *Leases*, for details on the future funding requirements related to our leases.

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. We have made royalty payments to the NCI in accordance with the patent license agreement. Refer to Note 9, *Commitments and Contingencies*, for further details.

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 will be due upon the initiation of our first sponsored Phase 1 clinical trial of a licensed product or licensed process in the field of use licensed under 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. No payments were made during the years ended December 31, 2021 and 2020.

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, 2021 and 2020, 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 twenty percent 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.

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") Accounting Standards Codification ("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 for our one open contract. 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). To date, we have not recognized any development, regulatory or commercial milestones or royalty revenue resulting from any of our collaboration arrangements. 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 options.

• 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.

• 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 the 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.

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-28 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, 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, 2021. Based on that evaluation, our principal executive officer and principal financial officer has concluded that as of December 31, 2021, our disclosure controls and procedures were effective as described below under "*Management's Report on Internal Control over Financial Reporting*."

Remediation of Material Weakness

In connection with the review of our financial statements as of and for the quarter ended June 30, 2021, we identified a material weakness in our internal control over financial reporting. 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. Our identified material weakness existing in our financial reporting process relates to the lack of sufficient accounting resources to execute certain controls related to the reconciliation and review of accounts in a timely manner.

Following the identification of the material weakness in our internal controls over financial reporting as of June 30, 2021, we prepared a remediation action plan and implemented that plan to improve the controls related to the reconciliation and review of accounts in a timely manner. We enhanced and revised the design of related existing internal controls, implemented incremental controls over our financial statement close process and hired new accounting staff. During the fourth quarter of 2021, we successfully completed the testing necessary to conclude that the material weakness has been remediated. The material weakness had no impact on any amounts reported in the financial statement for the fiscal year ended December 31, 2021 or for any previous period.

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, principal financial officer, and 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, principal financial officer, and principal accounting officer, we assessed our internal control over financial reporting as of December 31, 2021, 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, 2021, based on the criteria discussed above.

Inherent Limitations on Internal Controls

Our management, including our principal executive officer, principal financial officer, and principal accounting officer, does 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 judgements 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

Other than the changes described above, 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 28, 2022, Dr. Baffa notified us of his decision to resign from his position as our Chief Medical Officer, effective March 31, 2022, in order to pursue other opportunities.

In connection with Dr. Baffa's resignation, we entered into a letter agreement, or the Baffa Separation Agreement, to govern the terms of his separation. Under the Baffa Separation Agreement, subject to its due execution, in exchange for a release of claims and certain post-employment covenants, Dr. Baffa is entitled to receive a $155,000 lump sum cash payment and we have waived our right to recover half of his $160,000 sign-on bonus which we would otherwise be entitled to since he is departing after the first anniversary but before the second anniversary of his employment start date. Regardless of whether or not Dr. Baffa executes the Baffa Separation Agreement, we will continue paying Dr. Baffa's COBRA premiums for four months following the separation date. The Baffa Separation Agreement supersedes all prior agreements between the parties. In addition, the Baffa Separation Agreement includes confidentiality and intellectual property provisions which continue after Dr. Baffa's departure. Dr. Baffa has seven business days following execution in which he may rescind his resignation and revoke the Baffa Separation Agreement. The Baffa Separation Agreement will become effective upon the expiration of the seven business day revocation period.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Current Directors, Director Nominees And Executive Officers

Our Board of Directors

Set forth below are the names and certain information about each of our directors as of March 15, 2022. The information presented includes each director's age, principal occupation and business experience for the past five years and the names of other public companies of which he or she has served as a director during the past five years. In addition, the table contains information about the specific and particular experience, qualifications, attributes or skills of each current director and each nominee for director at the annual meeting that led the corporate governance and nominating committee to believe that such current director was appropriate for nomination at a previous annual meeting of stockholders and, in the case of each nominee for director at the annual meeting, that such nominee should serve on our board of directors following election at the annual meeting. Each of our directors serves for a one-year term until re-elected at our next annual meeting.

Name	Positions and Offices Held	Director Since	Age
Christopher Bowden M.D.	Director	2019	60
Kevin S. Boyle, Sr.	Chief Executive Officer and Director	2021	48
James Huang	Executive Chair	2020	56
Robert W. Postma	Director	2021	68
Mary Thistle	Director	2020	62
Jaime Vieser	Director	2020	52
Holger Weis	Director	2020	59

Christopher Bowden, M.D.
Director

Dr. Bowden, an oncology drug development executive with more than 20 years of leadership experience including the approval of several cancer medicines, has served as a member of our board of directors since October 2019. He was the Chief Medical Officer of Agios Pharmaceuticals from May 2014 to September 2021. Previously, Dr. Bowden was Vice President Product Development Oncology, at Genentech for eight years. From 2003 to 2006, he was the Executive Director for EMEA regions for Bristol-Myers Squibb. Earlier, Dr. Bowden held positions of increasing responsibility in oncology clinical development, at Pharmacia Corporation and Janssen Pharmaceutical. Prior to industry, Dr. Bowden was on the oncology faculty at the University of Virginia Health Science Center. From September 2017 to October 2020, Dr. Bowden served as a member of the board of directors of miRagen Therapeutics, Inc., a publicly traded biopharmaceutical company discovering and developing proprietary RNA-targeted therapies with a specific focus on microRNAs. Dr. Bowden received his M.D. from Hahnemann University School of Medicine followed by internal medicine training at Roger Williams Medical Center and the Providence VA Medical Center, Rhode Island. He completed his medical oncology fellowship at the National Cancer Institute Medicine Branch. Dr. Bowden is board certified in internal medicine and medical oncology.

Our board of directors believes that Dr. Bowden's extensive background in drug development and leadership experience at several leading life science and pharmaceutical companies qualifies him to serve on the board of directors.

Kevin S. Boyle, Sr.
Director

Kevin S. Boyle, Sr., was appointed our Chief Executive Officer and a member of our board of directors in August 2021. Mr. Boyle has over 20 years of experience in leading businesses in competitive and transformative situations and has a strong track record of delivering shareholder value. He is also an accomplished capital markets professional with strong banking relationships cultivated by raising over $2.0 billion in equity and debt capital over his career. Prior to joining the Company, Mr. Boyle served in various roles at Kuur Therapeutics, Inc. (formerly known as Cell Medica Ltd.). Mr. Boyle first served as Kuur's chief financial officer from February 2018 until January 2020. From January 2020 until May 2021, Mr. Boyle served as Kuur's chief executive officer where he led the company through a successful transformation, culminating in a $185 million acquisition in May 2021 by Athenex, Inc. (NASDAQ: ATNX). Following the acquisition, Athenex engaged Mr. Boyle as a consultant to assist in the integration of Kuur. Prior to joining Kuur, Mr. Boyle served as the chief financial officer of FloWorks International, LLC, Sigma3 Integrated Reservoir Solutions, Recover Care, and SPT Inc. Mr. Boyle graduated with a B.S. from Carnegie Mellon University and a J.D. from the University of Pennsylvania Carey Law School.

Our board of directors believes that Mr. Boyle's prior experience as a chief executive officer in the life sciences industry and significant fundraising experience qualifies him to serve on the board of directors.

James Huang
Director

Mr. Huang has served as a member of our board of directors since July 2020, our Chair from January 2021 until February 2021, and our Executive Chair since February 2021. Mr. Huang joined Kleiner Perkins Caufield & Byers China, or KPCB China, as a managing partner in 2011 and focuses on the firm's life sciences practice. Prior to joining KPCB China, Mr. Huang was a managing partner at Vivo Ventures, a venture capital firm specializing in life sciences investments. Before joining Vivo in 2007, Mr. Huang was president of Anesiva, a biopharmaceutical company focused on pain-management treatments. During his 20-year career in the pharmaceutical and biotech industry, he also held senior roles in business development, sales, marketing and R&D with Tularik Inc. (acquired by Amgen), GlaxoSmithKline LLC, Bristol-Myers Squibb and ALZA Corp. (acquired by Johnson & Johnson). Mr. Huang is also founding and managing partner of Panacea Venture, a global venture fund focusing on investments in innovative and transformative early and growth stage healthcare and life science companies. Mr. Huang is Chairman of the board at Kindstar Global (Beijing) Technology, Inc., Windtree Therapeutics, Inc., JHL Biotech, Inc., Tactiva Therapeutics, LLC, and Chime Biologics Limited and Director at CASI Pharmaceuticals Inc. and XW Laboratories Inc. Mr. Huang received an M.B.A. from the Stanford Graduate School of Business and a B.S. degree in chemical engineering from the University of California, Berkeley.

Our board of directors believes that Mr. Huang's extensive experience in life science investments and serving on the boards of directors of a number of life sciences and pharmaceutical companies qualifies him to serve on the board of directors.

Robert W. Postma
Director

Mr. Postma has served as a member of our board of directors since February 2021. Mr. Postma has also served as the president of WaterMill Asset Management Corp. ("WaterMill"), a company which he founded in July 1999. WaterMill actively trades in municipal bonds and equities, using the funds of Mr. Postma. Mr. Postma has over 44 years of trading experience and received a B.A. in Business and Economics from Lafayette College.

Our board of directors believes that Mr. Postma's management and trading experience allows Mr. Postma to provide financial guidance to us and qualifies him to serve on the board of directors.

Mary Thistle
Director

Ms. Thistle has served as a member of our board of directors since November 2020. Ms. Thistle has served as Special Advisor to the Bill & Melinda Gates Medical Research Institute, a non-profit biotech organization, since October 2020, and was its Chief of Staff from January 2018 until October 2020. Prior to then, she held senior leadership positions at Dimension Therapeutics, Inc., a gene therapy company, including serving as its Chief Operating Officer from 2016 to 2017 and Chief Business Officer from 2015 to 2016. Prior to joining Dimension Therapeutics, Inc., she spent six years at Cubist Pharmaceuticals, Inc., a biopharmaceutical company, where she held various leadership positions, including serving as its Senior Vice President, Business Development from 2014 to 2015, Vice President, Business Development from 2012 to 2013 and Senior Director, Business Development from 2009 to 2012. Prior to then, she held various positions at ViaCell, Inc. and PerkinElmer Inc. Ms. Thistle serves as a member of the boards of directors of Homology Medicines, Inc. (NASDAQ: FIXX), Entrada Therapeutics, Inc. (NASDAQ: TRDA) and the board of directors of private companies, Enterome SA and Cocoon Biotech Inc. Ms. Thistle holds a B.S. in Accounting from the University of Massachusetts, Boston.

Our board of directors believes that Ms. Thistle's perspective, financial expertise, business development and leadership experience at several biopharmaceutical companies provides her with the qualifications and skills to serve on the board of directors.

Jaime Vieser
Director

Mr. Vieser has served as a member of our board of directors since December 2020. Mr. Vieser currently manages Brushwood LLC, a private investment firm. From 2010-2017, he was a Managing Partner and co-principal of Castle Hill Asset Management LLC, a $2.7 billion asset manager and hedge fund focusing on high yield and distressed debt. Prior to founding Castle Hill, Mr. Vieser was responsible for Deutsche Bank's High Yield Sales and Trading Group in London from 1998 to 2008. Mr. Vieser originally joined Bankers Trust in New York in 1994 and worked in the Investment Banking/Leveraged Finance division. Mr. Vieser graduated from the University of Michigan with a degree in Economics and from the Cox School of Business at Southern Methodist University with a Master's in Business Administration.

Our board of directors believes that Mr. Vieser's financial expertise and investment experience allows Mr. Vieser to provide business to us and qualifies him to serve on the board of directors.

Holger Weis *Director*	Mr. Weis has served as a member of our board of directors since December 2020. Mr. Weis continues to serve as the principal of Weis Advisors, Inc., a company that provides consulting services to life science companies, since founding the company in April 2018. Prior to that, he served in a number of roles at DemeRx, Inc., a clinical stage pharmaceutical company developing non-addictive treatments for drug addiction, including serving as Chief Operating Officer and Chief Financial Officer from December 2011 to July 2017, and also as President from September 2014 to July 2017, and as a Consultant from July 2017 to April 2018. Earlier in his career, Mr. Weis served as the Chief Financial Officer of EnSA Holdings, LLC, a company that focuses on environmentally sustainable agriculture techniques and technologies for the production of rice, from August 2010 to November 2011. From 2006 to 2010, he served as the Vice President & Chief Financial Officer, Secretary and Treasurer of NovaVision, Inc., a therapeutic and diagnostic vision restoration company. Prior to that, he served as the Chief Financial Officer & Treasurer of GMP Companies, Inc., a company that develops and commercializes pharmaceutical, medical device and diagnostic technologies, from 2000 to 2005. Mr. Weis served as a Senior Manager at Ernst & Young, a multinational professional services company, from 1986 to 2000. Mr. Weis has co-authored a number of scientific papers and presentations and is an inventor on a number of patents and patent applications. Mr. Weis also serves on the board of directors of Jupiter NeuroSciences, Inc. Mr. Weis received a Bachelor of Business Administration in Accounting from the University of Georgia and is a Certified Public Accountant. Our board of directors believes that Mr. Weis's management and industry experience, as well as his financial expertise, qualify him to serve on the board of directors.

Agreement to Appoint a Director

Mr. Postma, Mr. Vieser and Mr. Weis were all nominated for election as directors at our last annual meeting pursuant to a certain settlement agreement we entered into with WaterMill and Mr. Postma. See Item 13 "*Certain Relationships and Related Transactions, and Director Independence—Certain Related-Party Transaction—WaterMill Settlement Agreement*" for more information.

Our Executive Officers

The following table sets forth certain information concerning our executive officers as of March 15, 2021.

Name	Position(s)	Age
Kevin S. Boyle, Sr.	Chief Executive Officer and Director	48
Michael Wong	Vice President, Finance	42
Raffaele Baffa, M.D., Ph.D.	Chief Medical Officer	61
Eleanor de Groot, Ph.D.	Executive Vice President, Operations	53
Melinda Lackey	Senior Vice President, Legal	45

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

Mr. Boyle's biography is included above under the section titled "Our Board of Directors."

Michael Wong
Vice President, Finance

Michael Wong was appointed to be our Vice President, Finance in September 2021. Mr. Wong has more than 17 years of experience leading teams and has had numerous management roles on complex finance projects. Previously, from February 2019 to September 2021, Mr. Wong was Director, Technical Accounting at McDermott International, Ltd., where he also served as Interim Head, Audit Services. Prior to joining McDermott, Mr. Wong was an Audit Senior Manager at Ernst & Young LLP. Mr. Wong was most recently based in Houston, but also spent 14 years, from 2005 to 2019, with Ernst & Young in both the London, U.K. and Toronto, Canada offices. Mr. Wong is a licensed CPA in Texas and Canada and has a Bachelor of Commerce from Queen's University, Canada.

Raffaele Baffa, M.D., Ph.D.
Chief Medical Officer

Dr. Baffa has served as our Chief Medical Officer since November 2020. Prior to joining us, Dr. Baffa served as the chief medical officer of Medisix Therapeutics, an immune engineering company developing novel cellular therapies to address T cell malignancies, from March 2020 to November 2020. From September 2018 until March 2020, Dr. Baffa served as the chief medical officer of Servier Pharmaceuticals. Prior to that, Dr. Baffa was Vice President and Therapeutic Area Head of Oncology, Global Clinical Development for Shire from February 2018 to September 2018 before its acquisition by Servier. Dr. Baffa has also held industry leadership positions as Executive Director, Early Oncology Development and Clinical Research at Pfizer from May 2015 to February 2018 and at Sanofi, where he was Head of Translational Sciences – External Science & Innovation, Global Biotherapeutics from November 2013 to May 2015 and Senior Director – Translational and Experimental Medicine, Early Development, Oncology from November 2010 to October 2013. Dr. Baffa earned an M.D. from University of Padova, School of Medicine, and a Ph.D. from University of Parma, both in Italy. As an associate professor at the Kimmel Cancer Center, Thomas Jefferson University in Philadelphia, he also served as Director of Urology Research and as Co-Director of the Genito-Urinary Cancer Program. Dr. Baffa has authored more than 100 peer-reviewed articles, invited articles and book chapters.

Eleanor de Groot, Ph.D.
Executive Vice President, Operations

Dr. de Groot has served as our Executive Vice President, Operations since September 2021. She previously served as our Executive Vice President, GM Cell Therapy beginning in January 2019 and oversaw our TCR-T cell therapy platform, including the collaboration with MD Anderson. She initially joined us in July 2015 as our Senior Vice President, Program Management and Business Development. Prior to joining us, Dr. de Groot was Vice President of Technical Operations and Project Planning and Management at Helsinn Therapeutics US, Inc. While at Helsinn and its predecessor companies, Sapphire Therapeutics and Rejuvenon Corporation, Dr. de Groot held multiple roles of increasing responsibility, leading technical operations, in particular chemistry, manufacturing, and controls development for its drug candidates from preclinical through Phase III, from April 2002 to July 2015. Prior to Helsinn, Dr. de Groot was a staff engineer at Guilford Pharmaceuticals (now Eisai) and a process engineer at Shell Chemical Company. She earned Ph.D. and M.S. degrees in chemical engineering from Stanford University in 1995 and 1991, respectively, and a B.S. in chemical engineering from Massachusetts Institute of Technology in 1990. Dr. de Groot received an M.B.A. degree from Rice University in 2014.

Melinda Lackey,
Senior Vice President, Legal

Ms. Lackey joined as our Senior Vice President, Legal in November 2021. She previously served as Counsel for Hogan Lovells from August 2021 until November 2021, where she supported life sciences companies at all stages with a focus on licensing and intellectual property. Ms. Lackey previously served as legal counsel Kuur Therapeutics, Inc. (and after its acquisition by Athenex, Inc., Athenex) from June 2018 until August 2021. Before industry, Ms. Lackey practiced law for 10 years focusing on intellectual property strategy and patent litigation from March 2008 until June 2018. Ms. Lackey has a J.D. from University of Houston Law Center (2007) and graduated from Texas Tech Health Sciences Center with an M.S. in medical microbiology and immunology (2003), focusing on molecular biology and immunology and a B.S. in Microbiology from Texas Tech University (1998).

There are no family relationships among any of our directors, director nominees or executive officers. None of our executive officers is related by blood, marriage or adoption to any of our directors, director nominees or executive officers.

Delinquent Section 16(A) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC reports of beneficial ownership and reports of changes in beneficial ownership in our securities. Based solely on a review of such reports filed electronically with the SEC, we believe that during 2021, all Section 16(a) filings applicable to our directors, officers, and 10% stockholders were filed on a timely basis, except as described in this section. One Form 3 that was filed by Michael Wong in connection with his appointment as an officer of our Company was not filed on a timely basis. One Form 3 that was filed by Raffaele Baffa in connection with his appointment as an officer of our Company was not filed on a timely basis.

Due to an administrative oversight, a Form 4 reporting grants of restricted stock and options to purchase our common stock awarded to Christopher Bowden, James Huang, Robert W. Postma, Mary Thistle, Jaime Vieser, Holger Weis and Kevin Buchi on March 4, 2021, were not filed until May 6, 2021.

Code of Ethics and Business Conduct

Our board of directors has adopted a Code of Ethics and Business Conduct which is applicable to all officers, directors and employees. The Code of Ethics and Business Conduct is intended to be designed to deter wrongdoing and promote honest and ethical behavior, full, fair, timely, accurate and understandable disclosure, compliance with applicable laws, rules and regulations, and prompt internal reporting of violations of this code. In addition to provisions that are applicable to officers, directors and employees generally, the Code of Ethics and Business Conduct contains provisions that are specifically applicable to our principal executive officer, principal financial officer and other senior financial officer(s). The Code of Ethics and Business Conduct is available on our website at *www.alaunos.com* and a copy may be obtained without charge upon written request to our legal department at our principal executive offices at 8030 El Rio Street, Houston, Texas 77054. Our website and its contents are not incorporated into this annual report.

Audit Committee

We have a separately designated standing audit committee. The current members of the committee are Mary Thistle, Jaime Vieser and Holger Weis.

Each member of the audit committee is an “independent director,” as such term is defined in Nasdaq Rule 5605(a)(2) and meets the criteria for independence set forth in Rule 10A-3(b)(1) under the Exchange Act. The board of directors has also determined that each of the audit committee members is able to read and understand fundamental financial statements and that at least one member of the audit committee has past employment experience in finance or accounting. The board of directors has determined that at least one member of the audit committee, Holger Weis, is an “audit committee financial expert,” as that term is defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Exchange Act.

Item 11. Executive Compensation

Executive Compensation Table

Summary Compensation Table

The following table sets forth information regarding compensation awarded to or earned by our named executive officers.

Name of Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Kevin S. Boyle, Sr. (2)	2021	200,000	147,500	1,435,000	2,790,638	315 (3)	4,573,753
Chief Executive Officer							
Heidi Hagen (4)	2021	287,500 (5)	200,000	387,900	1,795,770	40,254 (6)	2,711,424
Former Interim Chief Executive Officer	2020	—	—	—	—	—	—
Laurence James Neil Cooper (7)	2021	158,677	143,250	—	—	1,229,203 (8)	1,531,130
Former Chief Executive Officer	2020	573,000	917,000 (9)	722,857	703,855	91,210 (10)	3,007,922
Jill Buck (11)	2021	270,375	375,000 (12)	135,765	668,729	423,874 (13)	1,873,742
Former EVP, GM Gene Therapy	2020	356,416	119,952			12,315 (14)	488,684
Eleanor de Groot (15)	2021	382,667	480,875 (16)	219,056	1,078,991	12,428 (17)	2,174,017
EVP, Operations	2020	357,000	119,952	226,077	220,055	12,028 (18)	935,112
Raffaele Baffa	2021	465,000	302,875 (19)	252,419	—	13,976 (20)	1,034,270
Chief Medical Officer	2020	58,125	19,637	546,000	884,750	5,072 (21)	1,673,584

(1) These amounts have been calculated in accordance with ASC Topic 718. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. For a discussion of the assumptions relating to our valuations of these restricted stock awards and stock options, please see Note 3 to the financial statements included in this Annual Report on Form 10-K. These amounts reflect our accounting expense for these restricted stock awards and stock options and do not correspond to the actual value that may be recognized by our named executive officer.

(2) Mr. Boyle joined as our Chief Executive Officer in August 2021.

(3) Represents the dollar value of group term life insurance premiums we paid for the benefit of Mr. Boyle during 2021. We did not contribute to Mr. Boyle's 401(k) plan account pursuant to our matching program in 2021.

(4) Ms. Hagen resigned as our interim Chief Executive Officer in August 2021.

(5) $19,447 represents the amount we paid Ms. Hagen for her services as a member of our board of directors in 2021, and the remaining amount represents $287,500 in salary while serving as interim Chief Executive Officer.

(6) Of such amount, (i) $448 represents the dollar value of group term life insurance premiums we paid for the benefit of Ms. Hagen during 2021 and (ii) $20,359 represents accrued vacation paid at departure. We did not contribute to Ms. Hagen's 401(k) plan account pursuant to our matching program in 2021.

(7) Dr. Cooper resigned as our Chief Executive Officer, effective February 25, 2021 and left his position as a scientific advisor employee on April 9, 2021, at which time he became a consultant to us.

(8) Of such amount, (i) $774 represents the dollar value of group term life insurance premiums we paid for the benefit of Dr. Cooper during 2021, (ii) $11,600 represents the amount we contributed to Dr. Cooper's 401(k) plan account pursuant to our matching program, (iii) $44,625 represents accrued vacation paid at departure, (iv) $859,500 represents how much we paid Dr. Cooper in severance related to his resignation from his position as Chief Executive Officer and (v) $26,204 represents taxable perquisites for housing expenses, and (vi) $286,500 represents consulting fees paid to Dr. Cooper during 2021.

(9) Represents a fully vested restricted stock award with a grant value of $917,000 awarded to Dr. Cooper in connection with his separation. See the section titled "*Narrative to the Summary Compensation Table— Employment and Change in Control Agreements— Separation Agreement and Consulting Agreement with Laurence James Neil Cooper, M.D., Ph.D."* for additional information.

(10) Of such amount, (i) $1,548 represents the dollar value of group term life insurance premiums we paid for the benefit of Dr. Cooper during 2020, (ii) $78,462 represents taxable perquisites, including $77,848 for housing expenses and $614 for commuting expenses and (iii) $11,200 represents the amount we contributed to Dr. Cooper's 401(k) plan account pursuant to our matching program.

(11) Ms. Buck ceased being our Executive Vice President, GM Gene Therapy, effective September 15, 2021.

(12) Ms. Buck was paid $375,000 pursuant to her November 23, 2020 retention agreement under which she was paid the first two tranches which equaled 75% of her annual base compensation.

(13) Of such amount, (i) $383 represents the dollar value of group term life insurance premiums we paid for the benefit of Ms. Buck during 2021, (ii) $11,600 represents the amount we contributed to Ms. Buck's 401(k) plan account pursuant to our matching program, (iii) $26,891 represents accrued vacation paid at departure and (iv) $385,000 represents how much we paid Ms. Buck in severance related to her resignation from her position as Executive Vice President, GM Gene Therapy.

(14) Of such amount, (i) $540 represents the dollar value of group term life insurance premiums we paid for the benefit of Ms. Buck during 2020, (ii) $11,400 represents the amount we contributed to Ms. Buck's 401(k) plan account pursuant to our matching program, and (iii) $375 represents the amount paid for Ms. Buck's consulting services.

(15) Dr. de Groot was promoted from Executive Vice President, GM Cell Therapy, to Executive Vice President, Operations, effective August 30, 2021.

(16) Of such amount, Dr. de Groot was paid $375,000 pursuant to her November 23, 2020 retention agreement under which she was paid the first two tranches which equaled 75% of her annual base compensation.
(17) Of such amount, (i) $828 represents the dollar value of group term life insurance premiums we paid for the benefit of Dr. de Groot during 2021 and (ii) $11,600 represents the amount we contributed to Dr. de Groot's 401(k) plan account pursuant to our matching program.
(18) Of such amount, (i) $828 represents the dollar value of group term life insurance premiums we paid for the benefit of Dr. de Groot during 2020 and (ii) $11,200 represents the amount we contributed to Dr. de Groot's 401(k) plan account pursuant to our matching program.
(19) Of such amount, Dr. Baffa was paid $175,000 pursuant to his November 23, 2020 retention agreement under which he was paid the first two tranches which equaled 75% of his annual base compensation.
(20) Of such amount, (i) $2,376 represents the dollar value of group term life insurance premiums we paid for the benefit of Dr. Baffa during 2021 and (ii) $11,600 represents the amount we contributed to Dr. Baffa's 401(k) plan account pursuant to our matching program.
(21) Of such amount, (i) $297 represents the dollar value of group term life insurance premiums we paid for the benefit of Dr. Baffa during 2020 and (ii) $4,775 represents the amount we contributed to Dr. Baffa's 401(k) plan account pursuant to our matching program.

Narrative to Summary Compensation Table

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

Formal bonus plan goals were not set for 2021 because our CEO was not hired until August 2021. 2021 bonuses were paid out between 69% and 100% of target based on the Committee's assessment of performance. Our employment arrangements with our named executive officers provide that the executive may be eligible to earn an annual performance bonus of up to a target percentage of the executive's base salary, as described further below under the section titled "Employment and Change in Control Agreements."

In 2021, Mr. Boyle was granted an option to purchase 2,625,000 shares of our common stock, which option has an exercise price of $1.64 per share, and 875,000 shares of restricted common stock in connection with his appointment as our Chief Executive Officer. The new hire award was intended as an inducement for Mr. Boyle to join the Company.

Executive Retention

In the fourth quarter of 2020, our board of directors, following the recommendation of the compensation committee, granted certain of our named executive officers, including Drs. Baffa and de Groot and Ms. Buck, each a cash retention award, a portion of which was contingent upon achievement of certain patient dosing milestones in our TCR-T program. Dr. de Groot and Ms. Buck were each provided an award for $500,000, with 40% of the award payable if such individual remains employed with us on April 1, 2021, 35% of the retention award payable if such individual remains employed with us on September 1, 2021, and 25% of the retention award payable if such individual remains employed with us on December 1, 2021. Dr. Baffa was provided an award for $250,000, with 40% of the award payable if Dr. Baffa remains employed with us on April 1, 2021, 30% of the award payable if Dr. Baffa remains employed with us on September 1, 2021, and 30% of the award payable if Dr. Baffa remains employed with us on December 1, 2021. The final payment of the awards for each of Drs. Baffa and de Groot was contingent upon achievement of certain patient dosing milestones in our TCR-T program which were not achieved and therefore not paid. Dr. de Groot and Ms. Buck each received an amount equal to $375,000 and Dr. Baffa received $175,000. Ms. Buck was not employed with us on December 1, 2021 and so was not paid the third tranche of the retention award program.

Employment and Change in Control Agreements

We have the following employment agreements in place with our named executive officers.

Employment Agreement with Kevin S. Boyle, Sr.

Mr. Boyle has served as our Chief Executive Officer since August 2021 pursuant to an employment agreement entered into in August 2021. Mr. Boyle has an at-will employment relationship with us.

Base Salary. Mr. Boyle's annual base salary in 2021 was $600,000, pro-rated based on the number of days worked. Under his employment agreement, Mr. Boyle's annual base salary is subject to review by the board of directors or the compensation committee at least annually.

Annual Performance Bonus; Sign-on Bonus. Under his employment agreement, Mr. Boyle is eligible to receive an annual bonus based on his performance as determined by the board of directors or the compensation committee. The target amount of the annual performance bonus is 60% of his base salary, with the actual amount to be received determined by the board of directors or the compensation committee. Mr. Boyle also received a one-time sign-on bonus of $50,000, referred to as the Boyle Signing Bonus; provided that, in the event that his employment is terminated for cause or he resigns without good reason (as defined in the employment agreement) on or prior to August 30, 2022, Mr. Boyle shall be required to repay the Boyle Signing Bonus in full, subject to certain deductions and withholding obligations.

Equity Incentive Grants. In connection with his appointment as our Chief Executive Officer and pursuant to his employment agreement, effective as of August 24, 2021, the board of directors granted to Mr. Boyle an option to purchase 2,625,000 shares of our common stock, which option has an exercise price of $1.64 per share and the Company issued Mr. Boyle 875,000 shares of restricted common stock. Mr. Boyle is also eligible to receive equity awards as determined by the board of directors in its sole discretion.

Severance Provisions. If (i) we terminate Mr. Boyle for a reason other than death, disability or "Cause" (as that term is defined in his employment agreement), or (ii) Mr. Boyle resigns for "Good Reason" (as that term is defined in his employment agreement), Mr. Boyle will be entitled to receive a severance payment equal to the sum of (x) his then-current base salary and (y) the target amount of his annual performance bonus for the calendar year in which such termination occurs, which is hereinafter referred to as the Boyle Severance Payment Amount, payment of a one-time severance bonus in an amount equal to a pro-rata portion of the target amount of his annual performance bonus for the calendar year in which such termination occurs, plus payment of our portion of the contributions for medical and dental insurance coverage for twelve months, subject to Mr. Boyle's execution and delivery of a general release in favor of the Company. Mr. Boyle will also receive accelerated vesting of his equity incentive awards through, with respect to time-based equity incentive awards, the next twelve-month period immediately following the effective date of his termination and, with respect to performance-based equity incentive awards, the next applicable performance period immediately following the effective date of his termination. The accelerated time-based equity awards will be deemed fully exercisable or non-forfeitable, as applicable, as of the later of the termination date or the effective date of the separation agreement. Any vested equity incentive awards held by Mr. Boyle shall remain exercisable until the earlier of (x) the date that is three years following the termination of his employment and (y) the expiration of the applicable term of the award.

In the case of either (i) a termination by us for a reason other than death, disability or "Cause," or (ii) a resignation for "Good Reason," in each case that occurs within 90 days prior to and in connection with a "Change of Control" (as that term is defined in his employment agreement), or within 18 months after the occurrence of a "Change of Control," then, Mr. Boyle will be entitled to receive a lump sum payment in an amount equal to the product of the Boyle Severance Payment Amount multiplied by two, payment of a one-time severance bonus in an amount equal to a pro-rata portion of the target amount of his annual performance bonus for the calendar year in which such termination occurs, payment of the Company's portion of the contributions for health insurance coverage for eighteen months. In addition, all unvested time-based stock options and unvested awards of restricted stock held by Mr. Boyle will be accelerated and deemed to have vested as of the later of the termination date and the effective date of the separation. In addition, all performance-based equity awards will vest as if the applicable target performance goals were achieved as of the later of (x) the termination date and (y) the effective date of the separation. Additionally, all outstanding equity awards held by Mr. Boyle will remain exercisable until the earlier of (v) the date that is three years following the termination of employment and (w) the expiration of the applicable option term.

Non-competition and Non-solicitation. Mr. Boyle has entered into an invention, non-disclosure and non-competition agreement, which provides that he will not compete with us or solicit our clients or customers for a year after the termination or cessation of his employment with us, and further provides that he will not solicit our employees for one year after the termination or cessation of his employment with us.

Employment Agreement with Eleanor de Groot, Ph.D.

Dr. de Groot has served as our Executive Vice President, Cell Therapy since January 1, 2019, and previously as our SVP, Program Management & Business Development from July 13, 2015 to December 31, 2018. In April 2019, we entered into an employment agreement with Dr. de Groot, which was amended in November 2020. Dr. de Groot has an at-will employment relationship with us.

Base Salary. In 2021, Dr. de Groot received a base salary of $385,000. Under her employment agreement, Dr. de Groot's annual base salary is subject to review by the board of directors or the compensation committee at least annually.

Annual Performance Bonus. Under her employment agreement, Dr.de Groot is eligible to receive an annual bonus based on her performance as determined by the board of directors or the compensation committee. The target amount of the annual performance bonus is 40% of her base salary, with the actual amount to be received determined by the board of directors or the compensation committee.

Equity Incentive Grants. Dr. de Groot is eligible to receive equity awards as determined by the board of directors in its sole discretion from time to time.

Severance Provisions. If (i) we terminate Dr. de Groot for a reason other than death, disability or "Cause" (as that term is defined in her employment agreement), or (ii) Dr. de Groot resigns for "Good Reason" (as that term is defined in her employment agreement), Dr. de Groot will be entitled to receive a severance payment equal to twelve months of her then-current base salary, plus payment of our portion of the contributions for medical and dental insurance coverage for twelve months, subject to Dr. de Groot's execution and delivery of a general release in favor of the Company. In the case of either (i) a termination by us for a reason other than death, disability or "Cause," or (ii) a resignation for "Good Reason," in each case that occurs within 90 days prior to and in connection with a "Change in Control" (as that term is defined in her employment agreement), or within 18 months after the occurrence of a "Change in Control," the, in addition to the foregoing severance provisions, all unvested stock options and unvested awards of restricted stock held by Dr. de Groot at the time that such termination

occurs will be accelerated and deemed to have vested as of her employment termination date, and Dr. de Groot will be entitled to full target amount of her annual performance bonus for the calendar year in which such termination occurs.

Non-competition and Non-solicitation. Dr. de Groot has entered into an invention, non-disclosure and non-competition agreement, which provides that she will not compete with us or solicit our clients or customers for a year after the termination or cessation of her employment with us, and further provides that she will not solicit our employees for one year after the termination or cessation of her employment with us.

Employment Agreement with Raffaele Baffa, M.D., Ph.D.

Dr. Baffa has served as our Chief Medical Officer since November of 2020 pursuant to an employment agreement Baffa entered into in September 2020, which we subsequently amended in November 2020. Dr. Baffa has an at-will employment relationship with us.

Base Salary. Dr. Baffa's annual base salary in 2021 was $465,000. Under his employment agreement, Dr. Baffa's annual base salary is subject to review by the board of directors or the compensation committee at least annually.

Annual Performance Bonus. Under his employment agreement, Dr. Baffa is eligible to receive an annual bonus based on his performance as determined by the board of directors or the compensation committee. The target amount of the annual performance bonus is 40% of his base salary, with the actual amount to be received determined by the board of directors or the compensation committee.

Equity Incentive Grants. Dr. Baffa is also eligible to receive equity awards as determined by the board of directors in its sole discretion from time to time.

Severance Provisions. If (i) we terminate Dr. Baffa for a reason other than death, disability or "Cause" (as that term is defined in his employment agreement), or (ii) Dr. Baffa resigns for "Good Reason" (as that term is defined in his employment agreement), Dr. Baffa will be entitled to receive a severance payment equal to twelve months of his then-current base salary, plus payment of our portion of the contributions for medical and dental insurance coverage for twelve months, subject to Dr. Baffa's execution and delivery of a general release in favor of the Company. In the case of either (i) a termination by us for a reason other than death, disability or "Cause," or (ii) a resignation for "Good Reason," in each case that occurs within 90 days prior to and in connection with a "Change of Control" (as that term is defined in his employment agreement), or within 18 months after the occurrence of a "Change of Control," then, in addition to the foregoing severance provisions, all unvested stock options and unvested awards of restricted stock held by Dr. Baffa at the time that such termination occurs will be accelerated and deemed to have vested as of his employment termination date, and Dr. Baffa will be entitled to full target amount of his annual performance bonus for the calendar year in which such termination occurs.

Non-competition and Non-solicitation. Dr. Baffa has entered into an invention, non-disclosure, non-solicitation and non-competition agreement, which provides that he will not compete with us or solicit our clients or customers for a year after the termination or cessation of his employment with us, and further provides that he will not solicit our employees for one year after the termination or cessation of his employment with us.

Employment Agreement with Laurence James Neil Cooper, M.D., Ph.D.

Dr. Cooper served as our Chief Executive Officer from May 2015 until February 2021, at which point Dr. Cooper served as a scientific advisor employee of the Company. As a scientific advisor employee, Dr. Cooper continued receiving his base salary and remained eligible for our employee benefit programs pursuant to the terms of his employment agreement. On April 5, 2021, we entered into a separation agreement with Dr. Cooper, or the Cooper Separation Agreement, providing for his cessation of employment effective April 9, 2021 and a consulting agreement, or the Cooper Consulting Agreement, providing his continued consulting thereafter. For a description of the material terms of the Cooper Separation Agreement and the Cooper Consulting Agreement see below under "*Consulting Agreement with Laurence James Neil Cooper, M.D., Ph.D.*" Below is a summary of the material terms of Dr. Cooper's employment agreement in place during 2021 when he served as our Chief Executive Officer.

Base Salary. In 2021, Dr. Cooper received a base salary of $573,000. Under his employment agreement, his base salary was subject to review by the board of directors or the compensation committee at least annually.

Annual Performance Bonus. Under his employment agreement, Dr. Cooper was eligible to receive an annual bonus based on his performance as determined by the board of directors or the compensation committee. The target amount of the annual performance bonus was 200% of his base salary, with the actual amount to be received determined by the board of directors or the compensation committee.

Equity Incentive Grants. Dr. Cooper was eligible under his employment agreement to receive equity awards as determined by the board of directors in its discretion from time to time. Under certain circumstances, the vesting of Dr. Cooper's equity awards could have been accelerated in the event of a change in control or if Dr. Cooper's employment with us is terminated.

Expense Reimbursement. Under his employment agreement, Dr. Cooper was eligible for reimbursement of normal, usual and necessary expenses incurred by him in furtherance of our business and affairs, including reasonable travel and entertainment expenses and the ordinary and necessary expenses incurred in connection with his commute.

Non-competition and Non-solicitation. Dr. Cooper has entered into an invention, non-disclosure and non-competition agreement, which provides that he will not compete with us or solicit our clients or customers for a year after the termination or cessation of his employment with us, and further provides that he will not solicit our employees for one year after the termination or cessation of his employment with us.

Separation Agreement and Consulting Agreement with Laurence James Neil Cooper, M.D., Ph.D.

On April 5, 2021, we entered into the Cooper Separation Agreement, and the Cooper Consulting Agreement. Under the Cooper Separation Agreement, in exchange for a release of claims and certain post-employment covenants and in lieu of any severance benefits under his employment agreement, Dr. Cooper is entitled to receive continuing payments of his base salary and COBRA premiums for a period of 18 months, a cash payment of $143,250, representing a pro-rata target amount of his annual performance bonus for 2021, a fully-vested restricted stock award with a grant value of $917,000, which represented Dr. Cooper's 2020 annual bonus, and certain limited reimbursements for legal fees and housing. Dr. Cooper is not entitled to any equity acceleration in connection with his separation, however his equity awards are eligible to continue to vest pursuant to their terms based on his consulting services to us. The board of directors determined these severance benefits were appropriate to provide Dr. Cooper, considering the severance benefits provided under the terms of his employment agreement and his contributions to our Company.

The term of the Cooper Consulting Agreement commenced on Dr. Cooper's employment separation and continues for up to three years, subject to earlier termination by either Dr. Cooper or the Company, provided that if Dr. Cooper terminates the agreement within the first year of the term, our sole remedy will be the right to cause Dr. Cooper to reimburse us certain of his cash severance described in the Separation Agreement. If we terminate the Cooper Consulting Agreement before the first anniversary of the effective date without cause (as defined in the Cooper Consulting Agreement) or Dr. Cooper terminates the agreement within the first year for good reason (as defined in the Cooper Consulting Agreement), the non-competition and non-solicitation provisions described above will be deemed waived by us. Unless the Cooper Consulting Agreement is terminated by us with cause or by Dr. Cooper before the first anniversary of the effective date and without good reason, all unvested restricted stock or options will immediately vest as of the effective date of the termination. Under the Cooper Consulting Agreement, Dr. Cooper may earn consulting fees in amounts of up to $573,000 for the first year and $300,000 for each of the following two years and is also eligible for reimbursement of reasonable out-of-pocket business expenses. In addition, the Cooper Consulting Agreement includes confidentiality and intellectual property provisions. Dr. Cooper received $286,500 in fees under the Cooper Consulting Agreement in 2021.

Employment Agreement with Heidi Hagen

On February 24, 2021, the board of directors appointed Heidi Hagen as our Interim Chief Executive Officer, effective February 25, 2021. Effective February 25, 2021, we entered into an employment agreement with Ms. Hagen, governing the terms of her employment as our Interim Chief Executive Officer. The majority of the equity value was provided as stock options to require an increase in the stock price and to allow the timeframe required for the long-term price improvement as a reflection of the long drug development cycle from discovery to commercial product. Ms. Hagen stepped down as Interim Chief Executive Officer on August 30, 2021 in connection with Mr. Boyle's employment as our Chief Executive officer.

Base Salary; Sign on Bonus. Ms. Hagen's employment agreement provided for an annual base salary of $575,000, pro-rated for service, and a one-time sign-on bonus of $50,000.

Performance Bonus. While Ms. Hagen was entitled to receive certain performance bonuses if she remained employed as our Interim Chief Executive Officer after September 1, 2021, these were not paid as a result of the appointment of Mr. Boyle as our new Chief Executive Officer effective August 31, 2021. Ms. Hagen received a bonus in the amount of $150,000.

Equity Incentive Grants. In connection with her appointment as our Interim Chief Executive Officer and pursuant to her employment agreement, on March 4, 2021, the board of directors granted Ms. Hagen 90,000 restricted shares of our common stock, which were scheduled to vest on the one-year anniversary of the date of grant, subject to Ms. Hagen's continued employment with us through such vesting date. In addition, pursuant to her employment agreement, on March 4, 2021, the board of directors granted to Ms. Hagen an option to purchase 675,000 shares of our common stock, which option has an exercise price of $4.31 per share. The option was scheduled to vest in twelve equal monthly installments over the term of one year, subject to Ms. Hagen's continued employment with us through each such vesting date. Ms. Hagen's employment agreement provided that if Ms. Hagen's employment terminates either because a replacement, full-time chief executive officer has been hired, or because we terminate her employment without "Cause" (as defined in her employment agreement), then upon termination of her employment, Ms. Hagen's shares of restricted stock shall vest in full, and any unvested portion of Ms. Hagen's option grant shall vest in full and become exercisable immediately. Upon Ms. Hagen's resignation as the Company's Interim Chief Executive Officer on August 29, 2021, Ms. Hagen's 90,000 restricted stock and option grant of 675,000 shares vested in full.

Severance Provisions. Ms. Hagen's employment agreement provided that if she was terminated by us for any reason other than death, disability or Cause, then we would be obligated to pay to Ms. Hagen her base salary through the date of termination, any accrued vacation, and any expense reimbursement amounts for expenses incurred through the date of termination. If, within 30 days after the effective date of termination, Ms. Hagen executes a written general release, she will also be entitled to receive continuing payments of her base salary for a period of four months. In addition, unless her employment is terminated for Cause, we may be required to pay 100% of applicable COBRA premiums for Ms. Hagen for up to 12 months.

Employment Agreement with Jill Buck

Ms. Buck most recently served as our Executive Vice President, GM Gene Therapy, joining Alaunos in September 2015, and being promoted to Executive Vice President, Strategy and Operations in early 2021. Ms. Buck left the Company on September 15, 2021. Ms. Buck entered into an employment agreement dated April 23, 2019, which we subsequently amended in November 2020, as Executive Vice President, GM Gene Therapy. Ms. Buck had an at-will employment relationship with us.

Base Salary. In 2021, Ms. Buck received a base salary of $385,000. Under her employment agreement, Ms. Buck's annual base salary was subject to review by the board of directors or the compensation committee at least annually.

Annual Performance Bonus. Under her employment agreement, Ms. Buck was eligible to receive an annual bonus based on her performance as determined by the board of directors or the compensation committee. The target amount of the annual performance bonus is 40% of her base salary, with the actual amount to be received determined by the board of directors or the compensation committee.

Equity Incentive Grants. Ms. Buck was eligible to receive equity awards as determined by the board of directors in its sole discretion from time to time.

Severance Provisions. Ms. Buck's employment agreement provided that if (i) we terminated Ms. Buck for a reason other than death, disability or "Cause" (as that term is defined in her employment agreement), or (ii) Ms. Buck resigned for "Good Reason" (as that term is defined in her employment agreement), Ms. Buck was entitled to receive a severance payment equal to twelve months of her then-current base salary, plus payment of our portion of the contributions for medical and dental insurance coverage for twelve months, subject to Ms. Buck's execution and delivery of a general release in favor of the Company. In the case of either (i) a termination by us for a reason other than death, disability or "Cause," or (ii) a resignation for "Good Reason," in each case that occurs within 90 days prior to and in connection with a "Change in Control" (as that term is defined in her employment agreement), or within 18 months after the occurrence of a "Change in Control," all unvested stock options and unvested awards of restricted stock held by Ms. Buck at the time that such termination occurs would have been accelerated and deemed to have vested as of her employment termination date, and Ms. Buck would have been entitled to full target amount of her annual performance bonus for the calendar year in which such termination occurs.

In connection with her departure, Ms. Buck received $385,000, pursuant to the terms of her separation agreement.

Non-competition and Non-solicitation. Ms. Buck has entered into an invention, non-disclosure and non-competition agreement, which provided that she would not compete with us or solicit our clients or customers for a year after the termination or cessation of her employment with us, and further provides that she would not solicit our employees for one year after the termination or cessation of her employment with us.

Health and Benefits

All of our full-time employees and certain of our part-time employees are eligible to participate in our health and welfare benefit plans, including our medical, dental, life and long-term disability insurance plans. Our health and welfare benefit plans do not discriminate in scope, terms or operation in favor of our executive officers.

401(k) Plan

Our employees, including our named executive officers, are eligible to participate in our 401(k) plan. Our 401(k) plan is intended to qualify as a tax qualified plan under Section 401 of the Internal Revenue Code of 1986, as amended (the "Code"). Our 401(k) plan provides that each participant may contribute a portion of his or her pretax compensation, up to a statutory limit, which for most employees was $19,500 in 2021, with an additional "catch up" contribution of up to $6,500 permitted for employees age 50 and older, to the 401(k) plan. Employee contributions are held and invested by the 401(k) plan's trustee. In 2021, we matched employee contributions at a rate of 100% up to 4% of an employee's base salary contributed to the plan. We believe that this benefit is consistent with the practices of our peer companies, and therefore helps us to recruit and retain key talent at a minimal cost to us.

Outstanding Equity Awards at 2021 Fiscal Year-End

The following table sets forth information regarding option awards and restricted stock awards held as of December 31, 2021 by our named executive officers.

Name	Option Awards				Stock Awards		
	Number of Securities Underlying Unexercised Options		Option Exercise Price ($/Sh)(1)	Option Expiration Date	Shares or Units of Stock That Have Not Vested		
	Exercisable (#)	Unexercisable (#)			Number (#)		Market Value ($)(2)
Laurence James Neil Cooper	487,171		2.24	1/6/2029			
	176,133	88,067 (3)	4.21	1/29/2030			
					57,233	(4)	62,384
Heidi Hagen	93,922	— (5)	5.22	2/2/2022			
	675,000	—	4.31	2/2/2022			
Kevin S. Boyle, Sr.	164,062	2,460,938 (6)	1.64	8/29/2031			
					875,000	(7)	953,750
Eleanor de Groot	100,000	—	11.53	7/13/2025			
	172,671	—	2.24	1/6/2029			
	55,067	27,533 (8)	4.21	1/29/2030			
	95,297	285,891 (9)	4.31	3/4/2031			
					17,900	(10)	19,511
					38,119	(11)	41,550
Raffaele Baffa	125,000	375,000 (12)		6/30/2022			
					150,000	(13)	163,500
					53,764	(14)	58,603
Jill Buck	—	—	—	—	—		—

(1) Each stock option was granted with an exercise price equal to the fair market value of our common stock on the grant date.
(2) Market values are calculated based on the closing market price of our common stock as reported on the Nasdaq Global Select Market on December 31, 2021, which was $1.09 per share.
(3) Vests with respect to 22,017 shares on March 31, 2022, June 30, 2022, and December 31, 2022, and with respect to 22,016 on September 30, 2022.
(4) Vests with respect to 57,233 shares on December 31, 2022.
(5) Options expired on February 2, 2022.
(6) Vests with respect to 164,063 shares on February 28, 2022, August 30, 2022, February 28, 2023, August 30, 2023, February 28, 2024, August 30, 2024, February 28, 2025, and August 30, 2025 and with respect to 164,062 shares on May 30, 2022, November 30, 2022, May 30, 2023, November 30, 2023, May 30, 2024, November 30, 2024, and May 30, 2025.
(7) Such shares are subject to transfer and forfeiture restrictions that lapse with respect to 218,750 shares on each of August 30, 2022, August 30, 2023, August 30, 2024, and August 30, 2025.
(8) Vests with respect to 6,883 shares on each of March 31, 2022, June 30, 2022, and December 31, 2022 and with respect to 6,884 shares on September 30, 2022.
(9) Vests with respect to 23,824 shares on each of March 31, 2022, June 30, 2022, September 30, 2022, March 31, 2023, June 30, 2023, September 30, 2023, March 31, 2024, June 30, 2024, and September 30, 2024 and with respect to 23,825 shares on December 31, 2022, December 31, 2023, and December 31, 2024.
(10) Such shares are subject to transfer and forfeiture restrictions that lapse with respect to 17,900 shares on December 31, 2022.
(11) Such shares are subject to transfer and forfeiture restrictions that lapse with respect to 12,706 shares on December 31, 2022, December 31, 2023 and December 31, 2024.
(12) Vests with respect to 31,250 shares on February 16, 2022. The remaining unvested shares will be forfeited on March 31, 2022 and vested options will expire on June 30, 2022.
(13) Such shares will be forfeited on March 31, 2022.
(14) Such shares will be forfeited on March 31, 2022.

Payments Upon Separation

Severance and Change in Control Benefits

We have agreements with each of our named executive officers providing them with severance benefits, including double trigger cash and equity severance for termination in connection with a change-in-control, as further described in "*Employment and Change in Control Agreements*" above. The amounts and terms and conditions of these severance rights reflect the negotiations between each of our named executive officers and us at the time these documents were entered into, the benefits provided by our peer companies to similarly situated executives at the time they were negotiated, as well as our desire for internal pay equity among our executive officers. We believe that these

existing arrangements are consistent with market practices and are critical to attracting and retaining high quality executives. We also believe the involuntary termination benefits allow our executives to focus on normal business operations rather than worrying about how business decisions that may be in our best interest will impact their own financial security. We do not provide golden parachute excise tax gross ups.

Director Compensation Table

The following table sets forth information regarding the compensation earned for service on our board of directors by our non-employee directors during the year ended December 31, 2021. We reimburse members of our board of directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of directors and committee meetings.

Name	Fees Earned or Paid in Cash ($)	Option Awards (1) ($)	Stock Awards (1) ($)	Total ($)
Christopher Bowden	64,725	86,697	17,960	169,382
James Huang	88,788	173,394	35,915	298,097
Robert W. Postma (2)	61,236	465,208	10,775	537,219
Mary Thistle	76,175	517,226	21,550	614,951
Jaime Vieser	63,217	499,887	17,960	581,064
Holger Weis	75,325	499,867	17,960	593,152
Heidi Hagen (3)	19,446	—	—	19,446
Kevin Buchi (4)	27,028	86,697	17,960	131,685

(1) The amounts reported in the "Option Awards" and "Stock Awards" columns represent compensation expense recognized for financial statement purposes under ASC Topic 718. In the case of each of our directors, the option award and/or stock award was granted on March 4, 2021. For a discussion of the assumptions relating to our valuations of these stock options, please see Note 13 to the financial statements included in elsewhere in this Annual Report on Form 10-K. These costs reflect our accounting expense for these stock options and do not correspond to the actual value that may be recognized by the directors.
(2) Mr. Postma was appointed to the board of directors effective February 4, 2021.
(3) Ms. Hagen left the board of directors effective February 24, 2021, rejoined the board of directors effective August 30, 2021, and finally resigned from the board of directors effective November 2, 2021.
(4) Mr. Buchi resigned from the board of directors effective May 19, 2021.

Non-Employee Director Compensation

In 2021, each of our non-employee directors was compensated as described below:

- an annual cash retainer fee of $50,000 for service on the board of directors; and
- additional annual cash retainer fees for board committee service as follows:

	Chair	Member
Audit Committee	$ 20,000	$ 12,000
Compensation Committee	15,000	9,000
Corporate Governance and Nominating Committee	10,000	6,000

The executive chair of our board of directors also receives further annualized cash compensation of $40,000. All cash retainers were paid on a quarterly basis in arrears to non-employee directors who continue to serve as members of the board of directors on the last business day of each calendar quarter.

In 2021, the non-employee director equity compensation program was modified to provide an annual equity award for 75,000 options and 10,000 RSUs to be granted on the date of each of our annual shareholder meetings (our prior practice was to grant annual awards in December each year, with the last annual award under our historical director compensation program made in December 2019). The executive chair also receives an additional 75,000 annual options and an additional 10,000 annual RSUs to recognize his leadership and workload. The annual options vest in equal monthly installments over one year and the annual RSUs vest in full on the earlier of one-year from grant or the next annual shareholder meeting. The foregoing grants to non-employee directors joining our Board of Directors other than at an annual stockholder meeting will be prorated for the number of months remaining until our next annual stockholder meeting.

In addition, in connection with a director's initial election of the board of directors, he or she receives options to purchase 150,000 shares of our comment stock on the date of each new non-employee director's appointment to our board of directors. The directors who received this award in 2021 included Ms. Thistle, Mr. Postma, Mr. Weis and Mr. Vieser. One-thirty-sixths of the shares underlying these awards will vest in equal monthly installments commencing, in the case of Ms. Thistle on December 15, 2021, in the case of Mr. Postma on March 4, 2021 and in the

case of Mr. Weis and Mr. Vieser, on January 15, 2021. We also granted to all of our directors awards of options and restricted stock to reflect the stub period between January and May 2021, when the date of our annual meeting would become the new grant date of director awards. We agreed to provide directors an award equal to an annual grant of 75,000 options and 10,000 shares of restricted stock. These annual amounts were prorated to only cover the 5 months between January and May, and further pro-rated for those who spent less time on the board. In the case of Ms. Thistle, we provided her an award assuming six months of service, to recognize that she had not yet received any awards since her joining the board in November 2020. Each director was entitled elect to receive their equity grant in the form of restricted shares of our common stock, options to purchase shares of our common stock, or half restricted stock units and half options.

As set forth in its written charter, the compensation committee annually reviews director compensation practices in consultation with our compensation consultant and recommends any changes for adoption by the full board of directors. As such, the director compensation described above is subject to change at the discretion of the board of directors.

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

Securities Authorized for Issuance under Equity Compensation Plans

Our 2012 Equity Incentive Plan, or the 2012 Plan and our 2020 Equity Incentive Plan, or the 2020 Plan, are our only equity compensation plans approved by our stockholders. The following table sets forth certain information as of December 31, 2021 with respect to the 2012 Plan and 2020 Plan:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options (A)	Weighted-Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)) (C)
Equity compensation plans approved by stockholders:			
2012 Stock Option Plan	2,847,190	$ 3.99	—
2020 Equity Incentive Plan	7,818,679	$ 2.46	14,247,679
Total:	10,665,869	$ 2.87	14,247,679
Equity compensation plans not approved by stockholders:			
Inducement Awards	32,500	$ 4.59	—
Total:	32,500	$ 4.59	—

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to the beneficial ownership of common stock as of March 15 for:

- each person, or group of affiliated persons, who is known by us to be the beneficial owner of greater than five percent of our outstanding common stock;
- each of our directors and director nominees;
- each of our named executive officers named in the “Executive Compensation - Executive Compensation Table” section above; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities, or have the right to acquire such powers within 60 days. Common stock subject to options that are currently exercisable or exercisable within 60 days of March 15 are deemed to be outstanding and beneficially owned by the person holding the options. These shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. Except as otherwise indicated, all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. Percentage

ownership calculations are based on 216,127,443 shares outstanding as of March 15, 2022. Except as otherwise noted below, the addresses for persons listed in the table is c/o Alaunos Therapeutics, Inc., 8030 El Rio Street, Houston, Texas 77054.

Name of Beneficial Owner	Number of Shares Beneficially Owned Shares	Percentage of Common Stock Beneficially Owned (%) %
5% Stockholders:		
MSD Credit Opportunity Master Fund, L.P. (1)	22,101,509	9.9%
The Vanguard Group (2)	11,633,700	5.4%
BlackRock, Inc. (3)	16,764,972	7.8%
Discovery Capital Management (4)	13,346,493	6.2%
Level One Parties (5)	24,178,873	11.2%
State Street Corporation (6)	13,318,734	6.2%
Named Executive Officers and Directors:		
Kevin S. Boyle, Sr. (7)	1,213,125	*
Heidi Hagen (8)	145,889	*
Laurence James Neil Cooper (9)	2,752,338	1.3%
Eleanor de Groot (10)	690,848	*
Raffaele Baffa (11)	436,895	*
Jill Buck (12)	127,214	*
Christopher Bowden (13)	180,010	*
James Huang (14)	170,833	*
Robert W. Postma (15)	6,483,664	3%
Mary Thistle (16)	113,333	*
Jaime Vieser (17)	1,128,237	*
Holger Weis (18)	239,523	*
All executive officers and directors as a group (12 persons)	13,681,909	6.2%

*Represents ownership of less than one percent.

(1) Based in part on a Schedule 13G/A filed with the SEC on February 14, 2020 by MSD Partners, L.P., or MSD Partners. MSD Partners has shared voting power with respect to 15,151,516 shares of our common stock, and may be deemed to beneficially own 15,151,516 shares of our common stock. MSD Partners is the investment manager of, and may be deemed to beneficially own securities beneficially owned by, MSD Credit Opportunity Master Fund, L.P. MSD Partners (GP), LLC ("MSD GP") is the general partner of, and may be deemed to beneficially own securities beneficially owned by, MSD Partners. Each of Glenn R. Fuhrman, John C. Phelan and Marc R. Lisker is a manager of, and may be deemed to beneficially own securities beneficially owned by, MSD GP. The 22,101,509 shares includes 6,949,993 out of the 7,575,758 shares of common stock issuable upon the full exercise of a warrant, which is the number of shares issuable upon exercise as limited by the Beneficial Ownership Limitation (as defined below) as of March 15, 2022. Such warrant is only exercisable to the extent that the holder thereof, together with its affiliates, would beneficially own no more than 9.99% of the outstanding shares of our common stock after giving effect to such exercise (the "Beneficial Ownership Limitation"). As a result of the Beneficial Ownership Limitation, the number of shares that may be issued to the holder upon exercise of the warrant may change depending upon changes in the outstanding shares of our common stock. Upon 61 days' prior notice to the Company, the holder may increase, decrease or terminate the Beneficial Ownership Limitation. The address of MSD Credit Opportunity Master Fund, L.P. is c/o Maples Corporate Services Limited, P.O. Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

(2) Based solely on a Schedule 13G/A filed with the SEC on February 10, 2022 by The Vanguard Group, or Vanguard. Vanguard is the beneficial owner of 11,633,700 shares and has shared voting power with respect to 395,047 shares, sole dispositive power with respect to 11,076,829 shares and shared dispositive power with respect to 556,871 shares. Aggregate beneficial ownership reported by Vanguard includes beneficial ownership of its subsidiaries, Vanguard Asset Management, Limited, Vanguard Fiduciary Trust Company, Vanguard Global Advisors, LLC, Vanguard Group (Ireland) Limited, Vanguard Investments Australia Ltd, Vanguard Investments Canada Inc., Vanguard Investments Hong Kong Limited and Vanguard Investments UK, Limited. The address of Vanguard is 100 Vanguard Blvd., Malvern, PA 19355.

(3) Based solely on a Schedule 13G/A filed with the SEC on February 3, 2022 by Blackrock, Inc., or BlackRock. BlackRock, as a parent holding company, is the beneficial owner of 16,764,972 shares and has sole voting power with respect to 16,427,610 shares and sole dispositive power with respect to 16,764,972 shares. Aggregate beneficial ownership reported by BlackRock is on a consolidated basis and includes beneficial ownership of its subsidiaries, BlackRock Life Limited, Aperio Group, LLC, BlackRock Advisors, LLC, BlackRock (Netherlands) B.V., BlackRock Institutional Trust Company, National Association, BlackRock Asset Management Ireland Limited, BlackRock Financial Management, Inc., BlackRock Japan Co., Ltd., BlackRock Asset Management Schweiz AG, BlackRock Investment Management, LLC, BlackRock Investment Management (UK) Limited, BlackRock Asset Management Canada Limited,

BlackRock Investment Management (Australia) Limited, BlackRock Fund Advisors and BlackRock Fund Managers Ltd. The address of BlackRock. is 55 East 52nd Street, New York, New York 10055.

(4) Based solely on a Schedule 13G filed with the SEC on February 14, 2022 by Discovery Capital Management, LLC, or Discovery. Discovery is the beneficial owner of 13,346,493 shares and has shared voting power with respect to 13,346,493 shares and shared dispositive power with respect to 13,346,493 shares. Robert K. Citrone, the control person of Discovery, may be deemed to exercise voting and/or dispositive power over the shares held for the account of Discovery. Aggregate beneficial ownership reported by Discovery includes beneficial ownership of Discovery Global Opportunity Master Fund, Ltd., a Cayman Islands limited company. The address of Discovery is 20 Marshall Street, Suite 310, South Norwalk, CT 06854.

(5) Based solely on a Schedule 13G jointly filed with the SEC on February 11, 2022 by Robert D. Hardie, Mollie G. Hardie and Level One Partners, LLC (collectively, the "Level One Parties"). The Level One Parties beneficially own 24,178,873 shares. Robert D. Hardie is the beneficial owner of 10,226,937, and has shared voting and dispositive power with respect to 7,406,823 shares, and sole dispositive and voting power with respect 2,860,114. Molly G. Hardie is the beneficial owner of 7,675,213, and has shared voting and dispositive power with respect to 7,276,723 shares, and sole dispositive and voting power with respect 398,490. Level One Partners, LLC is the beneficial owner of 6,236,723 shares, and has shared voting and dispositive power with respect to all 6,236,723 shares. The address of the Level One Parties is 210 Ridge McIntire Road, Suite 350, Charlottesville, Virginia 22903.

(6) Based solely on a Schedule 13G filed with the SEC on February 11, 2022 by State Street Corporation. State Street Corporation is the beneficial owner of 13,318,734 shares and has shared voting power with respect to 12,875,132 shares and shared dispositive power with respect to 13,318,734 shares. Aggregate beneficial ownership reported by State Street Corporation includes beneficial ownership of its subsidiaries, SSGA Funds Management, Inc., State Street Global Advisors Limited, State Street Global Advisors, Australia, Limited, State Street Global Advisors Europe Limited, and State Street Global Advisors Trust Company. The address of State Greet Corporation is State Street Financial Center, 1 Lincoln Street, Boston, MA 02111.

(7) Consists of (i) 885,000 shares of common stock held by Mr. Boyle and (ii) 328,125 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(8) To the best of our knowledge, consists of (i) 145,889 shares of common stock held by Ms. Hagen.

(9) To the best of our knowledge, consists of (i) 2,067,017 shares of common stock held by Dr. Cooper and (ii) 685,321 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(10) Consists of (i) 237,106 shares of common stock held by Dr. de Groot and (ii) 453,742 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(11) Consists of (i) 280,645 shares of common stock held by Dr. Baffa and (ii) 156,250 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(12) To the best of our knowledge, consists of 127,214 shares of common stock held by Ms. Buck.

(13) Consists of (i) 4,167 shares of common stock held by Mr. Bowden and (ii) 175,843 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(14) Consists of (i) 108,333 shares of common stock held by Mr. Huang and (ii) 62,500 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(15) Consists of (i) 1,201,870 shares of common stock held by Mr. Postma, (ii) 4,250,000 shares of common stock held by Water Mill Asset Management Corp., where Mr. Postma serves as the principal, (iii) 3,574 shares of common stock held by the IRA of Mr. Postma's spouse, (iv) 946,970 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of March 15, 2022 and (v) 81,250 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(16) Consists of (i) 5,000 shares of common stock held by Ms. Thistle and (ii) 108,333 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(17) Consists of (i) 705,321 shares of common stock held by Mr. Vieser, (ii) 325,000 shares of common stock held in Uniform Transfer to Minors Act accounts by Mr. Vieser's children, and (iii) 97,916 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

(18) Consists of (i) 120,167 shares of common stock held by Mr. Weis, (ii) 19,000 shares of common stock held by Mr. Weis' spouse, (iii) 2,440 shares of common stock held by Mr. Weis' children, and (iv) 97,916 shares of common stock issuable upon the exercise of options exercisable within 60 days of March 15, 2022.

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

The following discussion relates to certain transactions that involve both the Company and one of our executive officers, directors, director nominees or five-percent stockholders, or any member of their immediate family, each of whom we refer to as a "related party." For purposes of this discussion, a "related-party transaction" is a transaction, arrangement or relationship:

- in which we participate;
- that involves an amount in excess of $120,000; and
- in which a related party has a direct or indirect material interest.

Related-Person Transaction Policy

We have a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person, directly or indirectly, are, were or will be participants in which the amount involved will or may reasonably be expected to exceed $120,000 in any calendar year. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any person who is, or at any time since the beginning of the Company's last fiscal year was, an executive officer, director, or nominee to become a director of the Company or a beneficial owner of more than 5% of any class of our voting securities, including any of such persons' immediate family members and any entity that such persons owned, controlled, held a control position in or held a 5% or greater beneficial ownership interest in.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related person transactions and to effectuate the terms of the policy.

In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to: the risks, costs and benefits to us; the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated; the availability of other sources for comparable services or products; and the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

Certain Related-Party Transactions

Except as described below, there have been no transactions since January 1, 2021 in which we have been a participant in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or holders of more than 5% of our common stock, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described elsewhere in this filing under the sections titled "*—Executive Compensation*" and "*—Director Compensation*."

Collaboration with PGEN and MD Anderson

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, 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., who served as the Company's Chief Executive Officer from May 2015 to February 2021 and was formerly a tenured professor of pediatrics at MD Anderson. In partial consideration for entering into the MD Anderson License, the Company issued MD Anderson an aggregate of 11,722,163 shares of common stock for which the Company incurred a $67.3 million charge recorded in 2015.

During the year ended December 31, 2021, the Company made payments of $0.1 million to MD Anderson compared to $0 during the year ended December 31, 2020. The net balance of cash resources on hand at MD Anderson available to offset expenses and future costs for the year ended December 31, 2021 was $0 and for the year ended December 31, 2020 was $8.1 million, which is included in other current assets on the Company's balance sheet.

WaterMill Settlement Agreement

On February 4, 2021, we entered into an agreement, or the Settlement Agreement, with WaterMill and Robert W. Postma (collectively, the "WaterMill Parties"). Pursuant to the Settlement Agreement, we increased the size of our board of directors from eight to nine directors and appointed Mr. Postma to fill the newly created directorship.

The Settlement Agreement included certain customary standstill restrictions applicable from February 4, 2021 until the date that was the earlier of (i) January 1, 2022 and (ii) thirty (30) calendar days prior to the nomination deadline for our 2022 annual meeting of stockholders, or the Standstill Period. During the Standstill Period, the WaterMill Parties were, among other things, restricted from engaging in any solicitation of proxies or written consents with respect to the election or removal of directors or, with certain exceptions, any other matter or proposal, or acquiring voting stock that would result in the WaterMill Parties having beneficial ownership of more than 9.9% of our outstanding voting stock.

Under the Settlement Agreement, we agreed that during the Standstill Period, we would nominate each of Mr. Postma, Jaime Vieser and Holger Weis for election at any stockholder meeting at which directors are to be elected and will recommend, support and solicit proxies for the election of each of Messrs. Postma, Vieser and Weis.

The Settlement Agreement also provided that at any meeting of our stockholders held prior to the expiration of the Standstill Period, the WaterMill Parties would vote all of their shares of our securities in accordance with the recommendation of our board of directors, with respect to the election, removal and/or replacement of directors. The WaterMill Parties retained the right to vote in their sole discretion with respect to any other publicly announced proposal not made in breach of the Settlement Agreement.

Further, pursuant to the Settlement Agreement, we agreed to reimburse the WaterMill Parties for up to $400,000 of their reasonable out-of-pocket fees and expenses out of a total of approximately $650,000 in fees and expenses actually incurred by the WaterMill Parties 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, we have fully reimbursed the WaterMill Parties an aggregate amount of $400,000. During the year ended December 31, 2021, we received $250,000 in insurance recoveries associated with legal expenses incurred on this matter.

Joint Venture with TriArm Therapeutics Ltd.

On December 18, 2018, we launched Eden BioCell, a joint venture with TriArm, to lead the commercialization of our *Sleeping Beauty*-generated CAR-T therapies in the People's Republic of China (including Macau and Hong Kong), Taiwan and Korea. Under our agreements with TriArm, we 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 us and TriArm and the parties share decision-making authority. TriArm agreed to contribute up to $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. In March 2021 and as announced by the Company in April 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. In September 2021, it was mutually agreed between the parties to dissolve the joint venture. The dissolution of the joint venture and the related entity is in progress. James Huang, who became a director of our Company in July 2020, and was appointed Chair of our board of directors in January 2021 and then Executive Chair of our board of directors in February 2021, was the founder and serves as managing partner of Panacea Venture, which is an investor in TriArm. Mr. Huang also serves as a member of Eden BioCell's board of directors.

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 TCR-T clinical programs. Heidi Hagen, who became a director of the Company in June 2019 and resigned November 2, 2021 and served as the Company's Interim Chief Executive Officer on February 25, 2021 through her resignation on August 30, 2021, is a co-founder and former officer, of Vineti. The Company recorded expenses of approximately $0.4 million during the year ended December 31, 2021 and $29,000 during the year ended December 31, 2020, for services performed by Vineti.

Indemnification Agreements

We have entered into an indemnification agreement with each of our directors. These indemnification agreements and our charter and our bylaws indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

Independence of the Board of Directors

Our board of directors has undertaken a review of the independence of our directors and considered whether any director has a relationship that, in the opinion of the board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a member of our board of directors. Based upon information requested from and provided by each director concerning such director's background, employment and affiliations, including family relationships, the board of directors has determined that all of our directors, other than Mr. Boyle and Mr. Huang are "independent directors," as such term is defined in Nasdaq Rule 5605(a)(2). In making these determinations,

our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

The board of directors has established three standing committees: an audit committee, a compensation committee and a corporate governance and nominating committee. Each committee operates under a charter that has been approved by the board of directors. Current copies of each committee's charter are posted on the "Investors—Corporate Governance" section of our website, *www.alaunos.com*. Our website and its contents are not incorporated into this Annual Report on Form 10-K.

The current members of the committees are as follows:

	Audit	Compensation	Nominating
Christopher Bowden, M.D.		X	X
Robert W. Postma		X	X*
Mary Thistle	X	X	
Jaime Vieser	X		X
Holger Weis	X*	X*	

* Committee Chairperson

Audit Committee

The current members of the audit committee are Mr. Holger Weis, who serves as the committee's Chair, Ms. Mary Thistle and Mr. Jaime Vieser. As set forth in the audit committee charter, the primary responsibility of the audit committee is to oversee our financial reporting processes and internal control system on behalf of the board of directors. In that regard, the audit committee is responsible for, among other things, the appointment, compensation, retention and oversight of the work performed by the independent registered public accounting firm employed by us.

Each member of the audit committee is an "independent director," as such term is defined in Nasdaq Rule 5605(a)(2) and meets the criteria for independence set forth in Rule 10A-3(b)(1) under the Exchange Act. The board of directors has also determined that each of the audit committee members is able to read and understand fundamental financial statements and that at least one member of the audit committee has past employment experience in finance or accounting. The board of directors has determined that at least one member of the audit committee, Holger Weis, is an "audit committee financial expert," as that term is defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Exchange Act.

The audit committee held seven meetings during 2021.

Compensation Committee

The current members of the compensation committee are Ms. Thistle, who serves as the committee's Chair, Dr. Christopher Bowden, Mr. Postma and Mr. Weis. As set forth in the compensation committee charter, the compensation committee reviews our compensation policies and practices and makes recommendations to the board of directors in connection with all compensation matters affecting our executive officers.

Each member of the compensation committee is an "independent director," as such term is defined in Nasdaq Rule 5605(a)(2) and meets the criteria for independence set forth in Rule 10A-3(b)(1) under the Exchange Act.

The compensation committee held ten meetings during 2021.

Corporate Governance and Nominating Committee

The current members of the corporate governance and nominating committee are Mr. Robert W. Postma, who serves as the committee's Chair, Dr. Christopher Bowden and Mr. Jaime Vieser. As set forth in the corporate governance and nominating committee charter, the primary responsibility of the corporate governance and nominating committee is to consider and make recommendations to the board of directors concerning the appropriate size, function and needs of the board of directors and its committees. In that regard, the corporate governance and nominating committee is, among other things, responsible for establishing criteria for membership on board of directors, recruiting and recommending candidates to fill newly created or vacant positions on the board of directors and reviewing any candidates recommended by stockholders. In addition, the corporate governance and nominating committee evaluates and assesses the performance of the board of directors as a whole and its committees.

Each member of the corporate governance and nominating committee is an "independent director," as such term is defined in Nasdaq Rule 5605(a)(2), and meets the criteria for independence set forth in Rule 10A-3(b)(1) under the Exchange Act.

The corporate governance and nominating committee held two meetings during 2021.

Item 14. Principal Accountant Fees and Services

Principal Accountant Fees and Services

The following table presents the aggregate fees billed by RSM US LLP for the years ended December 31, 2021 and 2020.

Fee Category	2021	2020
Audit Fees (1)	$ 325,960	$ 375,203
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 325,960	$ 375,203

(1) Represents fees billed for professional services provided to us in connection with the annual audit of our financial statements, the review of our quarterly condensed financial statements, the audit of the effectiveness of our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (2020 only), as well as audit services that are normally provided by an independent registered public accounting firm in connection with statutory and regulatory filings or engagements for those fiscal years, such as statutory audits, and administrative fees and out-of-pocket costs.

Other than as discussed above, we did not incur any fees of RSM US LLP for audit-related, tax or other services in 2021 or 2020.

All fees described above were pre-approved by the audit committee.

Pre-Approval Policy and Procedures

The audit committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm, RSM US LLP. The policy generally authorizes pre-approval by the audit committee of specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the audit committee's approval of the scope of the engagement of the independent registered public accounting firm or on an individual, explicit, case-by-case basis before the independent registered public accounting firm is engaged to provide each service. The pre-approval of services may be delegated to one or more of the audit committee's members, but the decision must be reported to the full audit committee at its next scheduled meeting.

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.
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.
4.7*	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended.
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).
10.12+	Employment Agreement by and between the Registrant and Laurence James Neil Cooper, M.D., Ph.D. dated as of May 5, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed May 7, 2015).
10.13+	Separation Agreement, dated April 5, 2021, by and between the Registrant and Dr. Laurence Cooper (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed April 9, 2021)
10.14+	Consulting Agreement, dated April 5, 2021, by and between the Registrant and Dr. Laurence Cooper (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed April 9, 2021).
10.15+	Employment Agreement, dated February 25, 2021, by and between the Registrant and Heidi Hagen (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed March 2, 2021).
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).
10.17*+	Employment Agreement, dated April 23, 2019, by and between the Registrant and Jill Buck.
10.18*+	Amendment to Employment Agreement, dated November 23, 2020, by and between the Registrant and Jill Buck.
10.19*+	Employment Agreement, dated April 23, 2019, by and between the Registrant and Eleanor de Groot.
10.20*+	Amendment to Employment Agreement, dated November 23, 2020, by and between the Registrant and Eleanor de Groot.
10.21*+	Employment Agreement, dated September 30, 2020, by and between the Registrant and Raffaele Baffa.
10.22*+	Amendment to Employment Agreement, dated November 23, 2020, by and between the Registrant and Raffaele Baffa.
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.
10.39*#	Fourth Amendment to Patent License Agreement, dated as of May 4, 2021, by and between the Registrant and the National Cancer Institute.
10.40*#	Fifth Amendment to Patent License Agreement, dated as of August 13, 2021, by and between the Registrant and the National Cancer Institute.
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.
10.45	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).
10.46	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).
10.47	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).
10.48	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).
10.49	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).
10.50	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).
10.51	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).

10.52*	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.
10.53*	Separation Agreement, dated March 28, 2022, by and between the Registrant and Dr. Raffaele Baffa.
21.1*	Subsidiaries of the Registrant.
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 they are not material and would likely cause competitive harm to Alaunos Therapeutics, Inc. if disclosed.

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 30, 2022

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

Date: March 30, 2022

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 30, 2022
/s/ Michael Wong Michael Wong	Vice President, Finance *(Principal Accounting Officer)*	March 30, 2022
/s/ Christopher Bowden Christopher Bowden	Director	March 30, 2022
/s/James Huang James Huang	Director	March 30, 2022
/s/ Robert W. Postma Robert W. Postma	Director	March 30, 2022
/s/ Mary Thistle Mary Thistle	Director	March 30, 2022
/s/ Jaime Vieser Jaime Vieser	Director	March 30, 2022
/s/ Holger Weis Holger Weis	Director	March 30, 2022

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 (collectively, the Company) as of December 31, 2021 and 2020, 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, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with 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.

Description of the Matter
As discussed in Note 3 to the financial statements, the Company accrues costs for clinical trials and preclinical studies based upon estimates of costs incurred through the balance sheet date that have yet to be invoiced by the contract research organizations, clinical study sites, laboratories, consultants, or other vendors. 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 Company's accrual for clinical trial and preclinical study expenses totaled $2.0 million at December 31, 2021 as disclosed in Note 6.

We identified the accruals for clinical trial and preclinical study expenses to be a critical audit matter because auditing the Company's accruals for clinical trial and preclinical study expenses is complex due to the fact that information necessary to estimate the expense is accumulated from multiple sources. In addition, in certain circumstances, the determination of the nature and level of services that have been received during the reporting period requires judgment because the timing and pattern of vendor invoicing may not correspond to the level of services provided and there may be delays in invoicing from clinical study sites and other vendors.

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 reviewed 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.
- We performed analytical procedures over fluctuations in accruals by clinical trial and preclinical studies or other significant work orders throughout the year and inspected subsequent invoices received from third parties to assess the impact to the accrual.

/s/ RSM US LLP

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

Boston, Massachusetts
March 30, 2022

Alaunos Therapeutics, Inc.

BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 76,054	$ 115,069
Receivables	1,111	4,665
Prepaid expenses and other current assets	1,666	10,855
Total current assets	78,831	130,589
Property and equipment, net	10,941	10,231
Right-of-use asset	4,420	4,650
Deposits	42	130
Other non-current assets	631	745
Total assets	$ 94,865	$ 146,345
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,368	$ 960
Current portion of long-term debt	7,868	—
Accrued expenses	6,076	16,589
Lease liability - current portion	729	819
Total current liabilities	16,041	18,368
Long-term debt	16,250	—
Lease liability - non-current portion	4,518	3,995
Total liabilities	$ 36,809	$ 22,363
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock $0.001 par value; 350,000,000 shares authorized, 216,127,443 shares issued and outstanding at December 31, 2021 and 250,000,000 shares authorized, 214,591,906 shares issued and outstanding at December 31, 2020	216	215
Additional paid-in capital	900,693	887,868
Accumulated deficit	(842,852)	(764,101)
Total stockholders' equity	58,057	123,982
Total liabilities and stockholders' equity	$ 94,865	$ 146,345

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,	
	2021	**2020**
Collaboration revenue	$ 398	**$** —
Operating expenses:		
Research and development	49,643	52,696
General and administrative	27,564	27,665
Property and equipment and right-of-use asset impairment	740	-
Total operating expenses	77,947	80,361
Loss from operations	(77,549)	(80,361)
Other income (expense), net	(1,202)	385
Net loss	$ (78,751)	$ (79,976)
Net loss applicable to common stockholders	$ (78,751)	$ (79,976)
Basic and diluted net loss per share	$ (0.37)	$ (0.38)
Weighted average number of common shares outstanding used to compute basic and diluted net loss per share	214,399,074	209,636,456

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	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2019	181,803,320	$ 182	$ 778,953	$ (684,125)	$ 95,010
Stock-based compensation	-	-	6,829	-	6,829
Exercise of employee stock options	252,799	-	442	-	442
Restricted stock awards	805,900	1	(1)	-	-
Cancelled restricted common stock	(194,897)	-	-	-	-
Issuance of common stock in connection with a public offering, net of commissions and expenses of $5,900	29,110,111	29	88,632	-	88,661
Issuance of common stock in connection with an at the market offering, net of commissions and expenses of $400	2,814,673	3	13,013	-	13,016
Net loss	-	-	-	(79,976)	(79,976)
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

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

Alaunos Therapeutics, Inc.

STATEMENTS OF CASH FLOWS

(in thousands)

	For the Twelve Months Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (78,751)	$ (79,976)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2,597	1,128
Property and equipment and right-of-use asset impairment	740	—
Amortization of financing costs	383	—
Stock-based compensation	10,774	6,829
(Increase) decrease in:		
Receivables	3,555	(1,335)
Prepaid expenses and other current assets	9,189	11,566
Right-of-use asset	(352)	(2,378)
Other noncurrent assets	201	(635)
Increase (decrease) in:		
Accounts payable	274	54
Accrued expenses	(10,512)	5,272
Lease liabilities	434	2,462
Net cash used in operating activities	(61,468)	(57,013)
Cash flows from investing activities:		
Purchases of property and equipment	(3,323)	(9,778)
Net cash used in investing activities	(3,323)	(9,778)
Cash flows from financing activities:		
Proceeds from long-term debt	25,000	—
Payment of debt issuance costs	(260)	—
Proceeds from the exercise of stock options	1,036	442
Issuance of common stock in connection with a public offering, net	—	88,661
Issuance of common stock in connection with at the market offerings, net	—	13,016
Net cash provided by financing activities	25,776	102,119
Net increase (decrease) in cash and cash equivalents	(39,015)	35,328
Cash and cash equivalents, beginning of period	115,069	79,741
Cash and cash equivalents, end of period	$ 76,054	$ 115,069
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ 630	$ —
Amounts included in accrued expenses and accounts payable related to property and equipment	$ 134	$ 471
Supplementary disclosure of noncash investing and financing activities		
Warrants issued with long-term debt	$ 1,016	$ —

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 will continue to seek a partner for this program and has also begun exploring potential synergies between this technology and its cell therapy programs. Costs incurred during the year ended December 31, 2021 under the program wind-down have not been material.

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, 2021, the Company had approximately $76.1 million of cash and cash equivalents. The Company's accumulated deficit at December 31, 2021 was approximately $842.9 million. Given its current development plans and cash management efforts, the Company anticipates cash resources will be sufficient to fund operations into the second quarter of 2023. The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. 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.

The Company's amended and restated certificate of incorporation authorizes it to issue 350,000,000 shares of common stock. As of December 31, 2021, there were 216,127,443 shares of common stock outstanding and an additional 33,620,711 shares of common stock reserved for issuance pursuant to outstanding stock options and warrants.

2. Financings

2021 Loan and Security Agreement

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

Effective December 28, 2021, the Company, entered into a First Amendment (the "Amendment") to the Loan and Security Agreement (the "Amended Loan and Security Agreement").

The Amended Loan and Security Agreement extends the interest-only period through August 31, 2022, and provides for an automatic extension through August 31, 2023, if certain funding and clinical milestones are met by August 31, 2022 (the "Amended Milestones"). The Amendment eliminated the Term B Tranche, which remained unfunded, leaving only the Term A Tranche (the "SVB Facility"). Under the Amended Loan and Security Agreement, the SVB Facility will mature on August 1, 2023; however, if the Company achieves the Amended Milestones on or prior to August 31, 2022, then the maturity will automatically extend to August 1, 2024.

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

February 2020 Public Offering

On February 5, 2020, the Company issued and sold 27,826,086 shares of its common stock at an offering price to the public of $3.25 per share, for aggregate net proceeds of approximately $84.8 million after deducting underwriting discounts and offering expenses paid by the Company. The offering was made pursuant to the Company's effective registration statement on Form S-3ASR (File No. 333-232283) previously filed with the Securities and Exchange Commission (the "SEC") and a prospectus supplement thereunder.

On March 10, 2020, the underwriters exercised their option to purchase an additional 1,284,025 shares. The net proceeds were approximately $3.9 million after deducting underwriting discounts and offering expenses paid by us.

At-the-Market Offering Program

In June 2019, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies, pursuant to which the Company may offer and sell, from time to time through Jefferies, shares of its common stock having an aggregate offering price of up to $100.0 million. Shares will be sold pursuant to the Company's effective registration statement on Form S-3ASR (File No. 333-232283), as previously filed with the SEC.

There were no sales under the Sales Agreement during the year ended December 31, 2021. During the year ended December 31, 2020, the Company issued and sold an aggregate of 2,814,673 shares for aggregate net proceeds of approximately $13.0 million after deducting underwriting discounts and offering expenses payable by us.

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.

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.

Impact of COVID-19 Pandemic

With the ongoing COVID-19 pandemic, the Company has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its business and operations. The Company continues to evaluate the impact of the COVID-19 global pandemic on patients, healthcare providers and its employees, as well as its operations and the operations of its business partners and healthcare communities. In response to the COVID-19 pandemic, the Company has implemented policies at its locations to mitigate the risk of exposure to COVID-19 by its personnel, including restrictions on the number of staff in any given research and development laboratory and a work-from-home policy applicable to the majority of its personnel. The extent to which the COVID-19 pandemic impacts the Company's business, clinical development and regulatory efforts and the value of its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the COVID-19 pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

Subsequent Events

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

Organizational Changes

On February 25, 2021, the Company announced that Heidi Hagen, formerly the Lead Independent Director, was appointed Interim Chief Executive Officer, replacing Laurence Cooper, M.D., Ph.D. Ms. Hagen also remained a member of the board of directors. Dr. Cooper also stepped down from his seat on the board of directors and has continued to support the Company's research and development, or "R&D," programs as a consultant.

On August 22, 2021, the board of directors appointed Kevin S. Boyle, Sr., as Chief Executive Officer of the Company, effective August 30, 2021. Effective upon Mr. Boyle's employment, Ms. Hagen resigned as the Company's Interim Chief Executive Officer but continued to serve as a member of the board of directors. Ms. Hagen resigned as member of the board of directors effective November 2, 2021.

On November 4, 2021, the Company provided written notice of termination of the consulting agreement by and between the Company and Danforth Advisors, LLC, a financial consultancy firm specializing in working with life sciences companies (the "Cunningham Consulting Agreement"). Pursuant to the terms of the Cunningham Consulting Agreement, Tim Cunningham, the Company's interim Chief Financial Officer and principal financial officer, provided services to the Company.

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 on its 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, are 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 chief operating decision maker, 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 and does not track expenses on a program-by-program basis.

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 ("FASB") Accounting Standards Codification ("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, 2021 and 2020 are as follows:

($ in thousands)

Description	Balance as of December 31, 2021	Fair Value Measurements at Reporting Date Using: 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	$ —	$ —

($ in thousands)

Description	Balance as of December 31, 2020	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$ 75,990	$ 75,990	$ —	$ —

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.

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 for further details.

Revenue Recognition from Collaboration Agreements

Revenue for the year ended December 31, 2021 consisted of $0.4 million and for the year ended December 31, 2020 consisted of $0. For the year ended December 31, 2021, the Company recognized revenue through its Collaboration Agreement with Solasia Pharma K.K. due to the achievement of a milestone, as further described in Note 9, *Commitments and Contingencies.*

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* (“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 judgement 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 multiple 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 (Note 12).

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 recognizes the full impact of its share-based employee payment plans in the statements of operations for each of the years ended December 31, 2021 and 2020 and did not capitalize any such costs on the balance sheets. The Company recognized $7.4 million of compensation expense related to stock options for the year ended December 31, 2021 and $4.3 million of compensation expense related to stock options for the year ended December 31, 2020. The Company recognized $3.4 million of compensation expense, related to restricted stock for the year ended December 31, 2021 and $2.5 million for the year ended December 31, 2020 (Note 13). The total compensation expense relating to vesting of stock options and restricted stock awards for the year ended December 31, 2021 was $10.8 million and $6.8 million for the year ended December 31, 2020. The following table presents share-based compensation expense included in the Company’s Statements of Operations:

	Year ended December 31,	
($ in thousands)	**2021**	**2020**
Research and development	$ 2,598	$ 2,098
General and administrative	8,176	4,731
Share based employee compensation expense	10,774	6,829

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 2021 was approximately $2.62 per share and was approximately $2.15 per share for the year ended December 31, 2020. 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:

	2021	2020
Risk-free interest rate	0.50 - 1.36%	0.36 - 1.68%
Expected life in years	5.50 - 6.25	5.75 - 6.25
Expected volatility	72.53 - 74.80%	71.11 - 74.41%
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:

	For the Year Ended December 31,	
	2021	2020
Net loss	$ (78,751)	$ (79,976)
Weighted-average common shares outstanding, basic and diluted	214,399,074	209,636,456
Net loss per share, basic and diluted	$ (0.37)	$ (0.38)

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, 2021 and 2020 as the result would be antidilutive. Such potential common shares on December 31, 2021 and 2020 consist of the following:

	December 31,	
	2021	2020
Stock options	10,665,869	6,832,386
Inducement stock options	32,500	588,333
Unvested restricted stock	1,198,580	786,280
Warrants	22,922,342	22,272,727
	34,819,291	30,479,726

New Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application. The Company adopted this standard effective January 1, 2021, with no material impact upon adoption.

4. Debt

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

($ in thousands)	December 31, 2021
Loan and Security Agreement	$ 25,209
Unamortized discount on Loan and Security Agreement	(1,091)
Total debt	24,118
Less: current portion of long-term debt	(7,868)
Long-term debt	$ 16,250

On August 6, 2021, the Company entered into a Loan and Security Agreement with SVB, or 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 a First Amendment, (the "Amendment") to the Loan and Security Agreement (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, 2021, interest on the outstanding loans was 7.75%. The Amended Loan and Security Agreement provides for an interest-only period which extends through August 31, 2022 and may be automatically extended through August 31, 2023 if, on or prior to August 31, 2022, SVB receives evidence satisfactory to it, confirming that the Company has (i) received at least $50.0 million in net cash proceeds from the sale of the Company's equity securities after the date of the Amended Loan and Security Agreement, on terms and conditions acceptable to SVB, and (ii) achieved positive data in the first cohort of the Library TCR-T Trial endorsed by an independent safety monitoring committee as a safe dose to proceed (together, the "Amended Milestones"). After the interest-only payment period, aggregate outstanding borrowings are payable in twelve consecutive, equal monthly installments of principal plus accrued interest.

All outstanding principal and accrued and unpaid interest under the SVB Facility and all other outstanding obligations under the Amended Loan and Security Agreement are due and payable on August 1, 2023; however, if the Company achieves the Amended Milestones on or prior to August 31, 2022, then the maturity will be automatically extended to August 1, 2024. In addition to the payment of the outstanding principal plus accrued interest due, the Company 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 the prepayment premium, of the SVB Facility, each payment of at least $5.0 million. Such prepayment premium would be 3.00% of the principal amount of the SVB Facility if prepaid prior to the first anniversary of the effective date, 2.00% of the principal amount of the SVB Facility if prepaid on or after the first anniversary of the effective date but prior to the second anniversary of the effective date and 1.00% of the principal amount of the SVB Facility if prepaid on or after the second anniversary of the effective date but prior to the maturity date. No amount that has been repaid may be reborrowed.

The Loan and Security Agreement required the Company to cash collateralize half of the sum of the outstanding principal amount of the term loans, plus an amount equal to 5.75% of the original principal amount of any portion of the SVB Facility actually extended, if the Company failed to achieve certain fundraising milestones on or prior to December 31, 2021.

The Amended Loan and Security Agreement revised the Company's cash collateralization obligation to require the Company to cash collateralize half of the sum of only 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 if the Company does not achieve the Amended Milestones on or prior to August 31, 2022. In the event a cash collateralization were to occur, so long as no event of default has occurred and, after subtracting the eighth scheduled payment of principal and interest on the SVB Facility, the sum of the aggregate of outstanding principal and accrued and unpaid interest, plus the final payment, is equal to or less than $9,770,933, then, within ten business days of the date of receipt of the eighth scheduled payment of principal and interest on the SVB Facility, SVB will release $2.5 million from the collateral account, so long as the balance in the collateral account after the release would equal or exceed $10.0 million. If no event of default has occurred and, after subtracting the tenth scheduled payment of principal and interest on the SVB Facility, the sum of the aggregate of outstanding principal and accrued and unpaid interest, plus the final payment, is equal to or less than $5,604,167, then, within ten business days of the date of receipt of the tenth scheduled payment of principal and interest on the SVB Facility, SVB will release a further $4.0 million from the collateral account, so long as the balance in the collateral account after the release would equal or exceed $6.0 million. 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, par value $0.001 per share in the aggregate, and (ii) up to an additional 432,842 shares of common stock, in the aggregate, in the event the Company achieves certain clinical milestones, in each case at an exercise price per share of $2.22.

In connection with the entry into the Amendment, 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 $1.2 million for the year ended December 31, 2021.

The fair value of the Amended Loan and Security Agreement as of December 31, 2021 approximates its face value due to proximity to the transaction.

5. Property and Equipment, net

Property and equipment, net, consists of the following:

	December 31,	
($ in thousands)	**2021**	**2020**
Office and computer equipment	$ 2,534	$ 869
Software	1,236	1,153
Leasehold improvements	9,474	7,457
Laboratory equipment	5,110	5,401
Construction-in-progress	—	313
	18,354	15,193
Less: accumulated depreciation	(7,413)	(4,962)
Property and equipment, net	$ 10,941	$ 10,231

Depreciation expense charged to the statement of operations for the year ended December 31, 2021 was $2.6 million and was $1.1 million for the year ended December 31, 2020. 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)	**2021**	**2020**
Clinical	$ 1,677	$ 4,450
Employee compensation	1,695	3,298
Professional services	825	3,993
Preclinical services	363	749
Manufacturing services	1,056	3,159
Accrued vacation	227	725
Payroll taxes and benefits	—	16
Other consulting services	66	199
Other	167	—
	$ 6,076	$ 16,589

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7. Related Party Transactions

Collaboration with PGEN and MD Anderson

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, 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., who served as the Company's Chief Executive Officer from May 2015 to February 2021 and was formerly a tenured professor of pediatrics at MD Anderson. In partial consideration for entering into the MD Anderson License, the Company issued MD Anderson an aggregate of 11,722,163 shares of common stock for which the Company incurred a $67.3 million charge recorded in 2015.

During the year ended December 31, 2021, the Company made payments of $0.1 million to MD Anderson compared to $0 during the year ended December 31, 2020. The net balance of cash resources on hand at MD Anderson available to offset expenses and future costs for the year ended December 31, 2021 was $0 and for the year ended December 31, 2020 was $8.1 million, which is included in other current assets on the Company's balance sheet.

Collaboration with Vineti Inc.

On July 9, 2020, the Company entered into a master service agreement and statement of work with Vineti, Inc., ("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 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, 2021, the Company recorded expenses of approximately $0.4 million and during the year ended December 31, 2020, the Company recorded expenses of approximately $29,000, for services performed by Vineti.

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 (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, we agreed to reimburse the WaterMill Parties for up to $400,000 of their reasonable out-of-pocket expenses out of a total of approximately $650,000 in fees and expenses actually incurred by the WaterMill Parties 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, we have fully reimbursed the WaterMill Parties an aggregate amount of $400,000.

Joint Venture with TriArm Therapeutics/Eden BioCell

On December 18, 2018, the Company and TriArm Therapeutics, Ltd. ("TriArm") launched Eden BioCell, Ltd. ("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, who became a director of the Company in July 2020, Chairman of the board of directors in January 2021, and Executive Chairman in February 2021, was the founder and serves as managing partner of Panacea Venture, which is an investor in TriArm. Mr. Huang also serves as a member of Eden BioCell's board of directors.

For the years ended December 31, 2021 and 2020, 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. 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 renewed through August 31, 2021. On April 22, 2021, the Company extended its lease for a portion of office space currently held at the Company's 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 has now been extended through August 31, 2026. As of December 31, 2021, and December 31, 2020, 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. We determined the aggregate carrying value of the asset group (approximately $1.4 million) 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. 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%. The Boston office has been fully vacated as of December 31, 2021.

On January 30, 2018, the Company entered into a lease agreement for office space in Houston, Texas at MD Anderson. Under the terms of the Houston lease agreement, the Company leased approximately 210 square feet and was required to make rental payments at an average monthly rate of approximately $1,000. This lease was terminated effective March 31, 2020.

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 $2,000 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 $17,000 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 $12,000 per month through February 2027, subject to an annual base rent increase of approximately 3.0% throughout the term.

On December 15, 2020, we entered into a second agreement with MD Anderson to lease additional space on MD Anderson's campus (the "2020 Lease"). As of December 31, 2021, the Company has approximately 32,148 square feet under lease from MD Anderson. The Company is initially required to make rental payments of approximately $37,000 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 our election.

The components of lease expense were as follows:

	Year Ended December 31,	
($ in thousands)	**2021**	**2020**
Operating lease cost	$ 1,394	$ 1,054
Total lease cost	$ 1,394	$ 1,054
Weighted-average remaining lease term (years)	5.58	6.19
Weighted-average discount rate	8.00%	8.00%

Cash paid for amounts included in the measurement of the lease liabilities were $1.3 million for the year-ended December 31, 2021. The Company recognized new operating lease assets obtained in exchange for operating lease liabilities of $1.4 million for the year-ended December 31, 2021.

As of December 31, 2021, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Maturity of Lease Liabilities	Operating Leases
2022	1,102
2023	1,132
2024	1,166
2025	1,201
2026	1,121
Thereafter	752
Total lease payments	6,474
Less: imputed interest	(1,227)
Present value of lease payments	$ 5,247

9. Commitments and Contingencies

License Agreements

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. As between the Company and PGEN, the terms of the License Agreement replaced and superseded the terms of: (a) that certain Exclusive Channel Partner Agreement by and between the Company and Precigen, dated January 6, 2011, as amended by the First Amendment to Exclusive Channel Partner Agreement effective September 13, 2011, the Second Amendment to the Exclusive Channel Partner Agreement effective March 27, 2015, and the Third Amendment to Exclusive Channel Partner Agreement effective June 29, 2016, which was subsequently assigned by Precigen to PGEN; (b) certain rights and obligations pursuant to that certain License and Collaboration Agreement effective March 27, 2015 between the Company, Precigen and ARES TRADING S.A., or Ares Trading, a subsidiary of Merck KGaA, or Merck, as assigned by Precigen to PGEN, or the Ares Trading Agreement; (c) that certain License Agreement between the Company, Precigen, and MD Anderson, with an effective date of January 13, 2015, or the MD Anderson License, which was subsequently assigned by Precigen and assumed by PGEN effective as of January 1, 2018; and (d) that certain research and development agreement between the Company, Precigen and MD Anderson with an effective date of August 17, 2015, or the 2015 R&D Agreement, and any amendments or statements of work thereto.

Pursuant to the terms of the 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 Ares Trading Agreement. 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 will pay PGEN an annual license fee of $100,000 and the Company has agreed to reimburse PGEN for certain historical costs of the licensed programs up to $1.0 million, which was fully paid during the year ended December 31, 2019.

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 digit to high-single digit on the net sales derived from the sales of any approved IL-12 products and CAR products. The Company 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. The Company will also pay PGEN twenty percent 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.

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In consideration of the Company's entry into the License Agreement, Precigen has forfeited and returned to the Company all shares of the Company's Series 1 preferred stock held by or payable to Precigen. The transaction represented a capital transaction between related parties and the date of settlement was accounted for during the License Agreement year ended December 31, 2018.

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 and on October 22, 2019, the Company entered into another amendment to the 2015 R&D Agreement, extending its term until December 31, 2026. During the year ended December 31, 2021, the Company made payments of $0.1 million to MD Anderson compared to $0 during the year ended December 31, 2020. The net balance of cash resources on hand at MD Anderson available to offset expenses and future costs for the year ended December 31, 2021 was $0 and for the year ended December 31, 2020 was $8.1 million, which is included in other current assets on the Company's balance sheet. For the year ended December 31, 2021, we recognized $8.1 million in expenses related to the 2015 R&D Agreement and for the year ended December 31, 2020, we recognized $12.2 million in expenses related to the 2015 R&D Agreement.

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.

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 R&D Agreement.

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

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On October 22, 2019, we entered into the 2019 Research and Development Agreement, or the 2019 R&D Agreement, with MD Anderson, pursuant to which the parties agreed to collaborate with respect to the TCR program. Under the 2019 R&D Agreement, the parties 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 intellectual property 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 outside the field of oncology and to develop and commercialize TCR products manufactured using viral gene transfer technologies, and a non-exclusive license for 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. For the year ended December 31, 2021, the Company incurred expenses of $0.5 million related to this agreement compared to $0 for the year ended December 31, 2020.

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 upon the occurrence of certain clinical milestones. As of December 31, 2021, none of the milestones have been met.

The MD Anderson Warrant and the shares of the Company's 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 National Cancer Institute, or 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.

Pursuant to the terms of the Patent License, we are required to pay the NCI a cash payment in the aggregate amount of $1.5 million payable in $0.5 million installments within sixty days, six-months, and the twelve-month anniversary of the effective date of the agreement for the Patent License. We also reimbursed the NCI for past patent expenses in the aggregate amount of approximately $46,000. Under the amendment to the patent license signed in January 2020, we agreed to pay the NCI a cash payment of $600,000 within sixty days of the amendment and under the amendment to the patent license signed in September 2020, we agreed to pay the NCI a cash payment of $411,000 within sixty days of the amendment.

The terms of the Patent License also 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.

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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 will be due upon the initiation of our first sponsored Phase 1 clinical trial of a licensed product or licensed process in the field of use licensed under 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.

For the year ended December 31, 2021 we expensed and made payments of $0.5 million and for the year ended December 31, 2020 we expensed and made payments of $1.5 million.

Cooperative Research and Development Agreement (CRADA) with the NCI

On January 9, 2017, we entered into a Cooperative Research and Development Agreement (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 our *Sleeping Beauty* technology, 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 and PGEN researchers.

We are responsible for providing 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 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 due to matters internal to the NCI and unrelated to our technology. 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. During the year ended December 31, 2021 we made payments of $1.25 million and during the year ended December 31, 2020 we made payments of $2.5 million, pursuant to the CRADA. For the third and fourth quarters of 2021, we were not required to make payments towards the program

as agreed with the NCI. 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.

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 other 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 single digit percentage 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, 2021, the Company paid fees under the terms of the license agreement of $0.1 million. No amounts were accrued or paid during the year ended December 31, 2020.

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. ("Solasia"), which was amended on July 31, 2014 to include an exclusive worldwide license. Pursuant to the 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 agreement, will receive a portion of all milestone and royalty payments made by Solasia to the Company in accordance with the terms of the license agreement with the Licensors. During the year ended December 31, 2021, the Company recorded $0.4 million of collaboration revenue under the collaboration agreement with Solasia in accordance with variable consideration guidance within ASC Topic 606, *Revenue from Contracts with Customers*. The collaboration revenue for the year ended December 31, 2021 related to a milestone event, which was met by Solasia related to a submission of approval application in Japan. No amounts were recorded or received during the year ended December 31, 2020.

10. Warrants

In connection with the Company's November 2018 private placement which 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 (the "November 2018 Warrants"). The November 2018 Warrants had an exercise price of $3.01 per share and have a five-year term. The relative 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.

The Company assessed whether the November 2018 Warrants require accounting as derivatives. The Company determined that the November 2018 Warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with FASB Accounting Standards Codification ("ASC") Topic 815, *Derivatives and Hedging*. As such, the Company has concluded the November 2018 Warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders' equity.

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 (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.

On October 22, 2019, the Company entered into the 2019 Agreement with MD Anderson. In connection with the execution of the 2019 Agreement, the Company issued MD Anderson a warrant to purchase 3,333,333 shares of common stock (the "MD Anderson Warrant"). 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 years ended December 31, 2021 and 2020, the Company did not recognize any expense related to the warrant as no work on the clinical milestones has begun.

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 are 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 Amendment, as described in Note 4, *Debt,* where the original warrants issued to SVB were amended and restated. As amended and restated, the warrants are for up to 649,615 shares of common stock, in the aggregate, at an exercise price per share of $1.16. The amended and restated warrants expire on August 6, 2031 and are 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 warrants due to the modification of the warrants.

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 Company expensed 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, 2021 and 2020 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, 2021 and 2020 are as follows:

	December 31,	
(in thousands)	**2021**	**2020**
Deferred tax assets:		
Net operating loss carryforwards	$ 164,486	$ 147,004
Start-up and organizational costs	21,705	25,909
Research and development credit carryforwards	39,817	37,183
Stock compensation	706	1,478
Capitalized acquisition costs	2,946	3,691
Lease liability	1,278	1,225
Depreciation	102	71
Other	156	135
	231,196	216,696
Less valuation allowance	(230,119)	(215,513)
Total deferred tax assets	1,077	1,183
Right-of-use asset	(1,077)	(1,183)
Total deferred tax liabilities	$ (1,077)	$ (1,183)
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, 2021, the Company has aggregate net operating loss carryforwards for federal tax purposes of approximately $639 million, of which approximately $342 million expires at various dates through December 31, 2037 and approximately $297 million can be carried forward indefinitely. The Company also has approximately $480 million of state net operating loss carryforwards available to offset future state taxable income, expiring at various dates through 2041. Additionally, the Company has approximately $40 million of federal and state research and development credits at December 31, 2021, expiring in varying amounts through 2041, which may be available to reduce future taxes.

The Company has provided a valuation allowance for the full amount of these 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 $14.6 million in 2021 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)	**2021**	**2020**
Federal income tax at statutory rates	21%	21%
State income tax, net of federal tax benefit	1%	3%
Research and development credits	2%	3%
Stock compensation	-1%	-1%
Sec. 162(m)	-2%	0%
Federal/state rate change	-2%	-2%
Change in valuation allowance	-19%	-24%
Effective tax rate	0%	0%

The Company adopted ASC 740, *Accounting for Uncertain Tax Positions* on January 1, 2007 ("ASC 740"). 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, 2021 and 2020.

The Company has not recognized any interest and penalties in the statement 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 2021.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief, and Economic Security ("CARES") Act into law which was an emergency economic stimulus package in response to the COVID-19 pandemic and its impact on the economy, public health, state and local governments, individuals and businesses. The Company has considered the legislation surrounding the impact of the CARES Act and the potential effects it may have on the Company. Some of the more significant provisions under the CARES Act include five-year carryback of net operating losses (Section 2303), Refundable AMT credit (Section 2305), relaxation of the limitation of adjusted taxable income (ATI) as determined under IRC Section 163(j) from 30% to 50% (Section 2306), and changes to qualified bonus improvement property (QIP) tax life and bonus depreciation eligibility allowing for a 15-year tax useful life an eligibility for 100% bonus depreciation (Section 2307). Due to the Company's history of US taxable losses, and use of MACRS and/or straight-line depreciation for tax purposes, there is no impact to the tax provision as a result of the enactment of the CARES Act. As of December 31, 2020, the Company has analyzed the provisions of the CARES Act and has recorded no income tax benefit or expense related to it.

13. Stock Option Plan

The Company adopted the 2012 Equity Incentive Plan (the "2012 Plan") in May 2012. Including subsequent increases, the Company had reserved 14,000,000 shares for issuance. On December 31, 2021, there are 2,847,190 shares reserved for issuance and no shares available for future grant.

The Company adopted the 2020 Equity Incentive Plan (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, 2021, 5,750,000 shares were registered, 7,818,679 shares reserved for issuance and 30,564 shares available for future grant.

As of December 31, 2021 the Company had outstanding options to its employees to purchase up to 9,208,236 shares of the Company's common stock, to its directors to purchase up to 1,397,633 shares of the Company's common stock, as well as options to consultants in connection with services rendered to purchase up to 60,000 shares of the Company's common stock.

Stock options to employees 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, 2021 amounted to $1.0 million and during the year ended December 31, 2020 amounted to $0.4 million. The intrinsic value of these options amounted to $0.8 million for the year ended December 31, 2021 and $0.3 million for the year ended December 31, 2020.

Stock option activity under the Company's stock options plans for the years ending December 31, 2021 and 2020 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, 2019	5,842,879	3.21		
Granted	2,222,368	3.39		
Exercised	(338,333)	2.01		
Cancelled	(886,195)	4.22		
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	8.67	$ —
Options exercisable, December 31, 2021	4,410,312	$ 3.85	7.53	$ —
Options exercisable, December 31, 2020	3,596,315	$ 4.17	6.90	$ 598
Options available for future grant at December 31, 2021	30,564			

The Company granted 400,000 inducement stock options on July 22, 2019 with exercise prices of $5.60, 65,000 on August 19, 2019 with exercise prices of $5.18, and 65,000 on November 21, 2019 with exercise prices of $4.59. The options vest ratably, over four years, commencing with one quarter on the first anniversary of the grant date and then quarterly thereafter. The options have a contractual term of ten years. These options were granted outside of the 2012 Plan and therefore, are not included in the table above. The grant date fair values were $1.5 million for the July 22, 2019 options, $231,000 for the August 19, 2019 options, and $193,000 for the November 21, 2019 options. As of December 31, 2021, 32,500 options are outstanding from all inducement stock options.

On December 31, 2021, total unrecognized compensation costs related to non-vested stock options outstanding amounted to $8.1 million. The cost is expected to be recognized over a weighted-average period of 2.1 years.

Restricted Stock

For the year ended December 31, 2021 the Company issued 1,601,224 shares of restricted stock and 805,900 in the year ended December 31, 2020 to employees and directors.

A summary of the status of restricted stock as of December 31, 2021 and 2020 is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2019	939,636	2.93
Granted	805,900	3.75
Vested	(764,359)	3.51
Cancelled	(194,897)	3.44
Non-vested, December 31, 2020	786,280	3.08
Granted	1,601,224	2.60
Vested	(754,137)	3.40
Cancelled	(434,787)	3.45
Non-vested, December 31, 2021	1,198,580	$ 2.10

As of December 31, 2021, there was $2.1 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 2.15 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 $0.7 million to the 401(k) Plan during the year ended December 31, 2021 and $0.5 million during the year ended December 31, 2020.

15. Joint Venture

On December 18, 2018, the Company entered into a Framework Agreement with TriArm whereby the parties will 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. On the closing date, upon the issuance and subscription of the shares, in respect of the aforementioned consideration, 10,000,000 ordinary shares were issued to the Company and 10,000,000 ordinary shares were issued to TriArm.

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. Eden BioCell will be responsible for certain milestone and royalty payments to related to the Company's license agreements with MD Anderson and PGEN. TriArm entered into a Master Services Agreement with Eden BioCell and contributed $10.0 million of cash on the closing date. TriArm also committed to contribute an additional $25.0 million to Eden BioCell over time through the achievement of specified milestones. TriArm and the Company each received a 50% equity interest in the joint venture in exchange for their contributions to Eden BioCell.

As of July 5, 2019, as a result of the design and purpose of 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 that most significantly impact its performance. Rather, 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 over the operations of Eden BioCell.

The Company determined that Eden BioCell was not a customer, and therefore, accounted for the transaction as the transfer of nonfinancial assets to be recognized at their fair value on the contribution date. The fair value of the intellectual property contributed to Eden BioCell had a de minimis value due to the early stage of the technology and the likelihood of clinical success. Due to the de minimis fair value of the intellectual property contributed, the Company did not record a gain or loss on this transaction and recognized no value for its equity-method investment.

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. Two patients have now been 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.

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.

In September 2021, TriArm and the Company mutually agreed to dissolve the joint venture.

For the years ended December 31, 2021 and 2020, Eden BioCell incurred a net loss. The Company continues to have no commitment to fund its operations.

Exhibit 3.1

CERTIFICATE OF AMENDMENT
OF THE
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
ZIOPHARM ONCOLOGY, INC.

ZIOPHARM Oncology, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. The name of the Corporation is ZIOPHARM Oncology, Inc., formerly known as EasyWeb, Inc. The date of filing of its original Certificate of Incorporation with the Secretary of State was May 16, 2005.

2. This Certificate of Amendment amends the provisions of the Corporation's Amended and Restated Certificate of Incorporation filed with the Secretary of State on April 26, 2006, as amended (the "Certificate of Incorporation").

3. Article 1 of the Certificate of Incorporation is hereby amended and restated to read as follows:

"1. *Name.* The name of the corporation is Alaunos Therapeutics, Inc. (the "Corporation")."

4. This Certificate of Amendment has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law.

5. All other provisions of the Certificate of Incorporation shall remain in full force and effect.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment to be signed by its Chief Executive Officer this 25th day of January, 2022.

/s/ Kevin S. Boyle, Sr.
Name: Kevin S. Boyle, Sr.
Title: Chief Executive Officer

CERTIFICATE OF AMENDMENT OF THE RESTATED CERTIFICATE OF INCORPORATION OF ZIOPHARM ONCOLOGY, INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

Ziopharm Oncology, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law proposing this Amendment of the Restated Certificate of Incorporation and declaring the advisability of this Amendment of the Restated Certificate of Incorporation, and authorizing the appropriate officers of the Corporation to solicit the consent of the shareholders therefor, which resolution setting forth the proposed amendment is as follows:

RESOLVED, that the first paragraph of section four of the Restated Certificate of Incorporation of the Corporation, as amended, be and it hereby is, deleted in its entirety and the following paragraph is inserted in lieu thereof:

"4. *Number of Shares.* The total number of shares of all classes of stock that the Corporation shall have authority to issue is Three Hundred Eighty Million (380,000,000) shares consisting of: Three Hundred Fifty Million (350,000,000) shares of common stock, $.001 par value per share ("Common Stock"); and Thirty Million (30,000,000) shares of preferred stock, $.001 par value per share ("Preferred Stock").

shareholders of the Corporation in accordance with the provisions of Section 242 of the General Corporation Law.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment of the Restated Certificate of Incorporation to be signed by its Chief Executive Officer this 19th day of May, 2021.

/s/ Heidi Hagen
Heidi Hagen
Interim Chief Executive Officer

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
of
ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology, Inc., a corporation organized and existing under the laws of the State of Delaware, hereby certifies as follows:

1. The name of the corporation is ZIOPHARM Oncology, Inc., formerly known as EasyWeb, Inc. The date of filing of its original Certificate of Incorporation with the Secretary of State was May 16, 2005.

2. That the Board of Directors of the corporation adopted resolutions, in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, setting forth a proposed Amended and Restated Certificate of Incorporation (the "Amended and Restated Certificate"), declaring the Amended and Restated Certificate to be advisable. The resolution setting forth the proposed Amended and Restated Certificate is as follows:

> "RESOLVED, that, subject to the approval of the holders of a majority of the outstanding shares of the Corporation's common stock, par value $.001 per share (the "Common Stock"), the Corporation's Amended Certificate of Incorporation shall be amended and restated in the manner set forth on the attached Exhibit A."

[Please see Exhibit A attached hereto.]

3. This Amended and Restated Certificate was duly adopted by vote of the stockholders of the Corporation in accordance with the provisions of Sections 222, 242 and 245 of the General Corporation Law of the State of Delaware.

4. That the Amended and Restated Certificate was duly adopted in accordance with the applicable provisions of Sections 222, 242 and 245 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the Corporation has caused this document to be executed in its corporate name as of this 26th day of April, 2006.

ZIOPHARM Oncology, Inc.

By: /s/ Jonathan Lewis

Jonathan Lewis, *Chief Executive Officer*

EXHIBIT A

1. *Name.* The name of the corporation is ZIOPHARM Oncology, Inc. (the "Corporation").

2. *Address; Registered Office and Agent.* The address of the Corporation's registered office is 2711 Centerville Road Suite 400, Wilmington, Delaware 19808. The Corporation may from time to time, in the manner provided by law, change the registered agent and the registered office within the State of Delaware. The Corporation may also maintain offices for the conduct of its business, either within or without the State of Delaware.

3. *Purposes.* The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the Delaware General Corporation Law.

4. *Number of Shares.* The total number of shares of all classes of stock that the Corporation shall have authority to issue is Two Hundred Eighty Million (280,000,000) shares consisting of: Two Hundred Fifty Million (250,000,000) shares of common stock, $.001 par value per share ("Common Stock"); and Thirty Million (30,000,000) shares of preferred stock, $.001 par value per share ("Preferred Stock").

The Preferred Stock may be divided into, and may be issued from time to time in one or more series. The Board of Directors of the Corporation (the "Board") is authorized from time to time to establish and designate any such series of Preferred Stock, to fix and determine the variations in the relative rights, preferences, privileges and restrictions as between and among such series and any other class of capital stock of the Corporation and any series thereof, and to fix or alter the number of shares comprising any such series and the designation thereof. The authority of the Board from time to time with respect to each such series shall include, but not be limited to, determination of the following:

a. The designation of the series;

b. The number of shares of the series and (except where otherwise provided in the creation of the series) any subsequent increase or decrease therein;

c. The dividends, if any, for shares of the series and the rates, conditions, times and relative preferences thereof;

d. The redemption rights, if any, and price or prices for shares of the series;

e. The terms and amounts of any sinking fund provided for the purchase or redemption of the series;

f. The relative rights of shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Corporation;

g. Whether the shares of the series shall be convertible into shares of any other class or series of shares of the Corporation, and, if so, the specification of such other class or series, the conversion prices

or rate or rates, any adjustments thereof, the date or dates as of which such shares shall be convertible and all other terms and conditions upon which such conversion may be made;

h. The voting rights, if any, of the holders of such series; and

i. Such other designations, powers, preference and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof.

5. *Election of Directors.* Unless and except to the extent that the by-laws of the Corporation (the "By-laws") shall so require, the election of directors of the Corporation need not be by written ballot.

6. *Limitation of Liability.* To the fullest extent permitted under the General Corporation Law, as amended from time to time, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Any amendment, repeal or modification of the foregoing provision shall not adversely affect any right or protection of a director of the Corporation hereunder in respect of any act or omission occurring prior to the time of such amendment, repeal or modification.

7. *Indemnification.*

7.1 *Right to Indemnification.* The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (a "Covered Person") who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity (an "Other Entity"), including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such Covered Person. Notwithstanding the preceding sentence, except as otherwise provided in Section 7.3, the Corporation shall be required to indemnify a Covered Person in connection with a Proceeding (or part thereof) commenced by such Covered Person only if the commencement of such Proceeding (or part thereof) by the Covered Person was authorized by the Board.

7.2 *Prepayment of Expenses.* The Corporation shall pay the expenses (including attorneys' fees) incurred by a Covered Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by applicable law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Covered Person to repay all amounts advanced if it should be ultimately determined that the Covered Person is not entitled to be indemnified under this Article 7 or otherwise.

7.3 *Claims.* If a claim for indemnification or advancement of expenses under this Article 7 is not paid in full within 30 days after a written claim therefor by the Covered Person has been received by the Corporation, the Covered Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the

burden of proving that the Covered Person is not entitled to the requested indemnification or advancement of expenses under applicable law.

7.4 *Nonexclusivity of Rights.* The rights conferred on any Covered Person by this Article 7 shall not be exclusive of any other rights that such Covered Person may have or hereafter acquire under any statute, provision of this Certificate of Incorporation, the By-laws, agreement, vote of stockholders or disinterested directors or otherwise.

7.5 *Other Sources.* The Corporation's obligation, if any, to indemnify or to advance expenses to any Covered Person who was or is serving at its request as a director, officer, employee or agent of an Other Entity shall be reduced by any amount such Covered Person may collect as indemnification or advancement of expenses from such Other Entity.

7.6 *Amendment or Repeal.* Any repeal or modification of the foregoing provisions of this Article 7 shall not adversely affect any right or protection hereunder of any Covered Person in respect of any act or omission occurring prior to the time of such repeal or modification.

7.7 *Other Indemnification and Prepayment of Expenses.* This Article 7 shall not limit the right of the Corporation, to the extent and in the manner permitted by applicable law, to indemnify and to advance expenses to persons other than Covered Persons when and as authorized by appropriate corporate action.

8. *Adoption, Amendment and/or Repeal of By-Laws.* In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board is expressly authorized to make, alter and repeal the By-laws, subject to the power of the stockholders of the Corporation to alter or repeal any By-law whether adopted by them or otherwise.

9. *Certificate Amendments.* The Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Amended and Restated Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by applicable law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Amended and Restated Certificate of Incorporation in its present form or as hereafter amended are granted subject to the rights reserved in this article.

Exhibit 4.6

THIS WARRANT AND THE SHARES ISSUABLE HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN SECTIONS 6.3 AND 6.4 BELOW, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE COMPANY, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

AMENDED AND RESTATED WARRANT TO PURCHASE STOCK

This AMENDED AND RESTATED WARRANT TO PURCHASE STOCK (as amended and in effect from time to time, this "**Warrant**") is issued as of the issue date set forth on Schedule I hereto (the "**Issue Date**") by the company set forth on Schedule I hereto (the "**Company**") to _____ in connection with that certain Loan and Security Agreement dated as of August 6, 2021 between them (as amended and/or modified and in effect from time to time, including without limitation by that certain First Amendment to Loan and Security Agreement of even date herewith, the "**Loan Agreement**"). This Warrant amends, restates and replaces that certain Warrant to Purchase Stock issued by Ziopharm Oncology, Inc., a Delaware corporation to _____ (the "**Original Warrant**") on August 6, 2021. The parties agree as follows:

SCHEDULE I. WARRANT PROVISIONS.

Warrant Section	**Warrant Provision**
Recitals – "Issue Date"	December 28, 2021.
Recitals – "Company"	ZIOPHARM ONCOLOGY, INC., a Delaware corporation.
1.1 – "Class"	Common Stock, $0.001 par value per share.
1.1 – "Exercise Price"	$1.16 per Share.
1.2– "Shares"	
4.1 – Share percentage as of the Issue Date	_____% of the Company's total fully-diluted issued and outstanding shares of capital stock.
6.1(a) – "Expiration Date"	August 6, 2031.

1.RIGHT TO PURCHASE SHARES.

a. Grant of Right. For good and valuable consideration, the Company hereby grants to _____ (together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "**Holder**") the right, and Holder is entitled, to purchase from the Company up to the number of fully paid and non-assessable shares (as determined pursuant to Section 1.2 below) of the class set forth on Schedule I hereto (the "**Class**"), at a purchase price per Share set forth on Schedule I hereto (the "**Exercise Price**"), subject to the provisions and upon the terms and conditions set forth in this Warrant.

b. Number of Shares. This Warrant shall be exercisable for the number of shares of the Class as set forth on Schedule I hereto (as may be adjusted from time to time in accordance with the provisions of this Warrant, the "**Shares**").

2.EXERCISE.

a. Method of Exercise. Holder may exercise this Warrant in whole or in part at any time and from time to time prior to the expiration or earlier termination of this Warrant, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 2.2 below, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Exercise Price for the Shares being purchased. Notwithstanding any contrary provision herein, to the extent that the original of this Warrant is an electronic original, in no event shall an original ink-signed paper copy of this Warrant be required for any exercise of a Holder's rights hereunder, nor shall this Warrant or any physical copy hereof be required to be physically surrendered at the time of any exercise hereof.

b. Cashless Exercise. On any exercise of this Warrant, in lieu of payment of the aggregate Exercise Price in the manner specified in Section 2.1 above, Holder may elect to surrender to the Company Shares having an aggregate value equal to the aggregate Exercise Price. If Holder makes such election, the Company shall issue to Holder such number of fully paid and non-assessable Shares determined by the following formula:

X = Y(A-B)/A

where:

X = the number of Shares to be issued to Holder;

Y = the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Exercise Price);

A = the fair market value (as determined pursuant to Section 2.3 below) of one Share; and

B = the Exercise Price.

c. Fair Market Value. If shares of the Company's common stock are then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a "**Trading Market**") and the Class is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of the Company's common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If shares of the Company's common stock are not then traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

d. Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Sections 2.1 or 2.2 above, the Company shall deliver to Holder a certificate (or, in the case of uncertificated securities, provide notice of book entry) representing the Shares issued to Holder upon such exercise and, if this Warrant has not been fully exercised and has not expired, a new warrant of like tenor representing the Shares not so acquired (or surrendered in payment of the aggregate Exercise Price).

e. Replacement of Warrant.

i. Paper Original Warrant. To the extent that the original of this Warrant is a paper original, on receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

ii. Electronic Original Warrant. To the extent that the original of this Warrant is an electronic original, if at any time this Warrant is rejected by any person (including, but not limited to, paying or escrow agents) or any such person fails to comply with the terms of this Warrant based on this Warrant being presented to such person as an

electronic record or a printout hereof, or any signature hereto being in electronic form, the Company shall, promptly upon Holder's request and without indemnity, execute and deliver to Holder, in lieu of electronic original versions of this Warrant, a new warrant of like tenor and amount in paper form with original ink signatures.

f. Treatment of Warrant Upon Acquisition of Company.

i. Acquisition. "**Acquisition**" means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company; (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company's domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company's (or the surviving or successor entity's) outstanding voting power immediately after such merger, consolidation or reorganization; or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company's then-total outstanding combined voting power. For the avoidance of doubt, "Acquisition" shall not include any sale and issuance by the Company of shares of its capital stock or of securities or instruments exercisable for or convertible into, or otherwise representing the right to acquire, shares of its capital stock to one or more investors for cash in a transaction or series of related transactions the primary purpose of which is a bona fide equity financing of the Company.

ii. Treatment of Warrant in Cash/Public Acquisition. In the event of an Acquisition in which the consideration to be received by the holders of the outstanding shares of the Class (in their capacity as such) consists solely of cash, solely of Marketable Securities (as hereinafter defined) or a combination of cash and Marketable Securities (a "**Cash/Public Acquisition**"), and the fair market value of one Share as determined in accordance with Section 2.3 above would be greater than the Exercise Price in effect as of immediately prior to the closing of such Cash/Public Acquisition, and Holder has not previously exercised this Warrant in full, then, in lieu of Holder's exercise of the unexercised portion of this Warrant, this Warrant shall, as of immediately prior to such closing (but subject to the occurrence thereof) automatically cease to represent the right to purchase Shares and shall, from and after such closing, represent solely the right to receive the aggregate consideration that would have been payable in such Acquisition on and in respect of all Shares for which this Warrant was exercisable as of immediately prior to the closing thereof, net of the aggregate Exercise Price therefor, as if such Shares had been issued and outstanding to Holder as of immediately prior to such closing, as and when such consideration is paid to the holders of the outstanding shares of the Class. In the event of a Cash/Public Acquisition in which the fair market value of one Share as determined in accordance with Section 2.3 above would be equal to or less than the Exercise Price in effect as of immediately prior to the closing of such Cash/Public Acquisition, then this Warrant will automatically and without further action of any party terminate as of immediately prior to such closing.

iii. Treatment of Warrant in non-Cash/Public Acquisition. Upon the closing of any Acquisition other than a Cash/Public Acquisition, the acquiring, surviving or successor entity shall assume this Warrant and the Company's obligations hereunder, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, at an aggregate Exercise Price equal to the aggregate Exercise Price in effect as of immediately prior to such closing, all subject to further adjustment from time to time thereafter in accordance with the provisions of this Warrant.

iv. Marketable Securities. "**Marketable Securities**" means securities meeting all of the following requirements (determined as of immediately prior to the closing of the Acquisition): (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Acquisition. Notwithstanding the foregoing provisions of this Section 2.6(d), securities held in escrow or subject to holdback to cover indemnification-related claims shall be

deemed to be Marketable Securities if they would otherwise be Marketable Securities but for the fact that they are held in escrow or subject to holdback to cover indemnification-related claims.

3.CERTAIN ADJUSTMENTS TO THE SHARES, CLASS AND EXERCISE PRICE.

a. Stock Dividends, Splits, Etc. If the Company declares or pays a dividend or distribution on the outstanding shares of the Class payable in additional shares of the Class (including fractional shares) or other securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder, the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Class by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased, even if such number would include fractional shares, and the Exercise Price shall be proportionately decreased. If the outstanding shares of the Class are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Exercise Price shall be proportionately increased and the number of Shares shall be proportionately decreased, even if such number would include fractional shares.

b. Reclassification, Exchange, Combination or Substitution. Upon any event whereby all of the outstanding shares of the Class are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, "Class" shall mean such securities and this Warrant will be exercisable for the number of such securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, at an aggregate Exercise Price equal to the aggregate Exercise Price in effect as of immediately prior to such event, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 3.2 shall similarly apply to successive reclassifications, exchanges, combinations, substitutions, replacements or other similar events.

c. Adjustment to Exercise Price on Cash Dividend. In the event that the Company at any time or from time to time prior to the exercise in full of this Warrant pays any cash dividend on the outstanding shares of the Class or makes any cash distribution on or in respect of all outstanding shares of the Class (other than a distribution of cash proceeds received by the Company in connection with an Acquisition described in Section 2.62.6(a)(i) above), then on and as of the date of each such dividend payment and/or distribution, the Exercise Price shall be reduced by an amount equal to the amount paid or distributed upon or in respect of each outstanding share of the Class; provided that in no event shall the Exercise Price be reduced below the then-par value, if any, of a share of the Class.

d. No Fractional Share. No fractional Share shall be issued upon exercise of this Warrant, and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of this Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash an amount equal to (a) such fractional interest, multiplied by (b)(i) the fair market value (as determined in accordance with Section 2.3 above) of a full Share, less (ii) the then-effective Exercise Price (the "**Fractional Share Value**"), unless Holder otherwise elects, in its sole discretion, to waive such payment. Notwithstanding any contrary provision herein, if this Warrant becomes exercisable for a fractional Share interest at any time or from time to time prior to the exercise in full of this Warrant, and the Company eliminates such fractional Share interest prior to any exercise of this Warrant, then the then-effective Exercise Price shall be reduced by an amount equal to the Fractional Share Value, unless Holder otherwise elects, in its sole discretion, to waive such reduction.

e. Certificate as to Adjustments. Within a reasonable time following each adjustment of the Exercise Price, Class and/or number of Shares pursuant to the terms of this Warrant, the Company, at its expense, shall deliver a certificate of its Chief Financial Officer or other authorized officer to Holder setting forth the adjustments to the Exercise Price, Class and/or number of Shares and the facts upon which such adjustments are based. The Company shall, at any time and from time to time within a reasonable time following Holder's written request and at the Company's expense, furnish Holder with a certificate of its Chief Financial Officer or other authorized officer setting forth the then-current Exercise Price, Class and number of Shares and the computations or other determinations thereof.

4.REPRESENTATIONS AND COVENANTS OF THE COMPANY.

a. Representations and Warranties. The Company represents and warrants to, and agrees with, Holder as follows:

i. Intentionally Omitted.

ii. Intentionally Omitted.

iii. All Shares which may be issued upon the exercise of this Warrant, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under the Company's Certificate of Incorporation or Bylaws, each as amended and in effect from time to time (the "**Charter Documents**"), any stockholder agreement (to the extent Holder is then a party thereto or otherwise subject thereto) or applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of shares of the Class and other securities as will be sufficient to permit the exercise in full of this Warrant.

iv. Intentionally Omitted.

b. Notice of Certain Events. If the Company proposes at any time to:

i. declare any dividend or distribution upon the outstanding shares of the Class, whether in cash, stock or other securities or property and whether or not a regular cash dividend;

ii. intentionally omitted;

iii. effect any redemption, reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Class; or

iv. effect an Acquisition, or to liquidate, dissolve or wind up the Company.

then, in connection with each such event, the Company shall give Holder (pursuant to Section 6.5 below):

1. in the case of the matters referred to in (a) above, at least seven (7) Business Days prior written notice of the earlier to occur of the effective date thereof or the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Class will be entitled thereto) or for determining rights to vote, if any; and

2. in the case of the matters referred to in (c) and (d) above, at least seven (7) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event and such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such event giving rise to the notice).

c. Certain Company Information. The Company will provide such information requested by Holder from time to time, within a reasonable time following each such request, that is reasonably necessary to enable Holder to comply with Holder's accounting or reporting requirements.

5.REPRESENTATIONS AND COVENANTS OF HOLDER.

Holder represents and warrants to, and agrees with, the Company as follows:

a. Investment Representations.

i. Purchase for Own Account. This Warrant and the Shares to be acquired upon exercise hereof are being acquired for investment for Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares.

ii. Disclosure of Information. Holder is aware of the Company's business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions of and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

iii. Investment Experience. Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities for an indefinite period of time, and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

iv. Accredited Investor Status. Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Act.

v. The Act. Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act or registered or qualified under the securities laws of any state, and are issued in reliance upon specific exemptions therefrom, which exemptions depend upon, among other things, the bona fide nature of the Holder's investment intent as expressed herein. Holder understands that the Company is under no obligation to so register or qualify this Warrant, the Shares or such other securities. Holder understands that this Warrant and the Shares issued upon any exercise hereof are "restricted securities" under applicable federal and state securities laws and must be held indefinitely unless subsequently registered under the Act and registered or qualified under applicable state securities laws, or unless exemptions from such registration and qualification are otherwise available. Holder is aware of the provisions of Rule 144 promulgated under the Act.

b. No Stockholder Rights. Without limiting any provision of this Warrant, Holder agrees that as a Holder of this Warrant it will not have any rights (including, but not limited to, voting rights) as a stockholder of the Company with respect to the Shares issuable hereunder unless and until the exercise of this Warrant and then only with respect to the Shares issued on such exercise.

c. Intentionally Omitted.

d. Confidential Information. Holder agrees to treat and hold all information provided by the Company pursuant to this Warrant in confidence in accordance with the provisions of Section 12.8 of the Loan Agreement (regardless of whether the Loan Agreement shall then be in effect).

6.MISCELLANEOUS.

a. Term; Automatic Cashless Exercise Upon Expiration.

i. Term. Subject to the provisions of Section 2.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Pacific time, on the expiration date set forth on Schedule I hereto (the "**Expiration Date**") and shall be void thereafter; provided that if the Company does not deliver to Holder written confirmation of the fair market value of a Share pursuant to Section 6.1(b) below, then the Expiration Date shall automatically be extended until the earlier to occur of (i) such date as the Company delivers such written confirmation and (ii) one (1) year after the Expiration Date.

ii. Automatic Cashless Exercise upon Expiration. In the event that, upon the Expiration Date, the fair market value of one Share as determined in accordance with Section 2.3 above is greater than the Exercise Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 2.2 above as to all Shares for which it shall not previously have been exercised, and the Company shall, within a reasonable time following Holder's written request, deliver a certificate (or, in the case of uncertificated securities, provide notice of book entry) representing the Shares issued to Holder upon such exercise. If shares of the Company's common stock are not then traded in a Trading Market, the Company shall deliver to Holder, prior to the Expiration Date, written confirmation of the fair market value of a Share (as determined pursuant to Section 2.3 above) to be used in determining whether this Warrant shall automatically exercise on the Expiration Date pursuant to this Section 6.1(b).

b. Legends. Each certificate or notice of book entry evidencing Shares shall be imprinted with a legend in substantially the following form (together with such additional legends as may be required by the Charter Documents or under any stockholder agreement (to the extent Holder is then a party thereto or otherwise subject thereto)):

> THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN AMENDED AND RESTATED WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO _____ DATED DECEMBER 28, 2021, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

c. Compliance with Securities Laws on Transfer. This Warrant and the Shares issued upon exercise hereof may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company). The Company shall not require Holder to provide an opinion of counsel if the transfer is to any affiliate of Holder; provided that any such transferee is an "accredited investor" as defined in Regulation D promulgated under the Act.

d. Transfer Procedure. Subject to the provisions of Section 6.3 and upon providing the Company with written notice, Holder and any subsequent Holder may transfer all or part of this Warrant or the Shares issued upon exercise of this Warrant to any transferee; provided that in connection with any such transfer, SVB Financial Group or any subsequent Holder will give the Company notice of the portion of the Warrant and/or Shares being transferred with the name, address and taxpayer identification number of the transferee, and Holder will surrender this Warrant, or the certificates or other evidence of such Shares or other securities, to the Company for reissuance to the transferee(s) (and to Holder if applicable); and provided further, that any subsequent transferee shall make substantially the representations set forth in Section 5.1 above and shall agree in writing with the Company to be bound by all of the terms and conditions of this Warrant; and provided further, that the transfer of any Shares issued on exercise hereof shall be subject to the provisions of the stockholder agreements to the extent Holder is then a party thereto or otherwise subject thereto.

e. Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 6.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

All notices to the Company shall be addressed as follows until Holder receives notice of a change in address:

f. Amendment and Waiver. Notwithstanding any contrary provision herein or in the Loan Agreement, this Warrant may be amended and any provision hereof waived (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by Holder and any party against which enforcement of such amendment or waiver is sought.

g. Counterparts; Electronic Signatures; Status as Certificated Security. This Warrant may be executed by one or more of the parties hereto in any number of separate counterparts, all of which together shall constitute one and the same instrument. The Company, Holder and any other party hereto may execute this Warrant by electronic means and each party hereto recognizes and accepts the use of electronic signatures and the keeping of records in electronic form by any other party hereto in connection with the execution and storage hereof. To the extent that this Warrant or any agreement subject to the terms hereof or any amendment hereto is executed, recorded or delivered electronically, it shall be binding to the same extent as though it had been executed on paper with an original ink signature, as provided under applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act. The fact that this Warrant is executed, signed, stored or delivered electronically shall not prevent the transfer by any Holder of this Warrant pursuant to Section 6.4 or the enforcement of the terms hereof. To the extent that the original of this Warrant is an electronic original, this Warrant, and any copies hereof, shall NOT be deemed to be a "certificated security" within the meaning of Section 8102(a)(4) of the California Commercial Code. Physical possession of the original of this Warrant or any paper copy thereof shall confer no special status to the bearer thereof.

h. Headings. The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

i. Business Days. "**Business Day**" means any day that is not a Saturday, Sunday or a day on which banks in California are closed.

7. GOVERNING LAW, VENUE AND JURY TRIAL WAIVER; JUDICIAL REFERENCE.

a. Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.

b. Jurisdiction and Venue. The Company and Holder each irrevocably and unconditionally submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Warrant shall be deemed to operate to preclude Holder from bringing suit or taking other legal action in any other jurisdiction to enforce a judgment or other court order in favor of Holder. The Company expressly, irrevocably and unconditionally submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and the Company hereby irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby irrevocably and unconditionally consents to the granting of such legal or equitable relief as is deemed appropriate by such court. The Company hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to the Company in accordance with Section 6.5 of this Warrant and that service so made shall be deemed completed upon the earlier to occur of the Company's actual receipt thereof of three (3) days after deposit in the U.S. mails, proper postage prepaid.

c. Jury Trial Waiver. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE COMPANY AND HOLDER EACH WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS WARRANT, THE LOAN AGREEMENT OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR THE PARTIES' AGREEMENT TO THIS WARRANT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

d. Judicial Reference. **WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY**, if the waiver of the right to a trial by jury in Section 7.3 above is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure Sections 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure Section 644(a). Nothing in this Section 7.4 shall limit the right of any party at any time to exercise self-help remedies or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this Section 7.4.

e. Survival. This Section 7 shall survive the termination of this Warrant.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused this Amended and Restated Warrant to Purchase Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

COMPANY:

ZIOPHARM ONCOLOGY, INC.

By: _____

Name: Kevin Boyle Sr.

Title: Chief Executive Officer

By: _____

Name: _____

Title: _____

APPENDIX 1

Form of Notice of Exercise of Warrant

a. The undersigned Holder hereby exercises its right to purchase _____ shares of the Common Stock of ZIOPHARM Oncology, Inc. (the "**Company**") in accordance with the attached Amended and Restated Warrant to Purchase Stock (the "**Warrant**"), and tenders payment of the aggregate Exercise Price for such shares as follows:

[ ] Check in the amount of $_____ payable to the order of the Company enclosed herewith

[ ] Wire transfer of immediately available funds to the Company's account

[ ] Cashless exercise pursuant to Section 2.2 of the Warrant, resulting in the issuance of _____ shares of the Common Stock of the Company

[ ] Other [Describe] _____

b. Please issue a certificate or certificates (or evidence of book entry) representing the Shares in the name specified below:

_____
Holder's Name

_____

_____
(Address)

c. By its execution below and for the benefit of the Company, Holder hereby makes each of the representations and warranties set forth in Section 5.1 of the Warrant as of the date hereof.

HOLDER

By: _____
Name: _____
Title: _____
(Date): _____

Exhibit 4.7

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of the securities of Alaunos Therapeutics, Inc. (the "Company" "we," "us," and "our") that are registered under Section 12 of the Securities Exchange Act of 1934, as amended. This description also summarizes relevant provisions of Delaware law. The following summary does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws, copies of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.7 is a part, and are incorporated by reference herein. We encourage you to read our certificate of incorporation, our bylaws and the applicable provisions of Delaware law for additional information.

General

Our authorized capital stock consists of 380,000,000 shares, comprised of 350,000,000 shares of common stock, par value $0.001 per share, and 30,000,000 shares of preferred stock, par value $0.001 per share.

Our common stock is listed on The Nasdaq Stock Market LLC under the trading symbol "TCRT."

Common Stock

Voting Rights. The holders of our common stock are entitled to one vote for each outstanding share of common stock owned by such stockholder on every matter properly submitted to the stockholders for their vote. Stockholders are not entitled to vote cumulatively for the election of directors. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. At any meeting of the stockholders, a quorum as to any matter shall consist of the holders of a majority of the votes entitled to be cast on the matter, except where a larger quorum is required by law, by our certificate of incorporation or by our bylaws.

Dividend Rights. Holders of our common stock are entitled to receive ratably dividends and other distributions of cash or any other right or property as may be declared by our board of directors out of our assets or funds legally available for such dividends or distributions. The dividend rights of holders of common stock are subject to the dividend rights of the holders of any series of preferred stock that may be issued and outstanding from time to time.

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, holders of our common stock would be entitled to share ratably in our assets that are legally available for distribution to stockholders after payment of liabilities. If we have any preferred stock outstanding at such time, the holders of such preferred stock may be entitled to distribution and/or liquidation preferences that require us to pay the applicable distribution to the holders of preferred stock before paying distributions to the holders of common stock.

Rights and Preferences. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

The transfer agent and registrar for any series of preferred stock will be set forth in the applicable prospectus supplement.

Preferred Stock

Pursuant to our amended and restated certificate of incorporation, our board of directors has the authority, without stockholder approval, subject to limitations prescribed by law, to provide for the issuance of up to 30,000,000 shares of preferred stock in one or more series, and by filing a certificate pursuant to the applicable law of the State of

Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each series and any qualifications, limitations or restrictions thereof, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

We will fix the designations, voting powers, preferences and rights of the preferred stock of each series, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the Commission, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of that series of preferred stock. This description will include:

- the title and stated value;
- the number of shares offered;
- the liquidation preference per share;
- the purchase price per share;
- the dividend rate(s), period(s) and/or payment date(s) or method(s) of calculation for dividends;
- whether dividends are cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- our right, if any, to defer payment of dividends and the maximum length of any such deferral period;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provision for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock, including the conversion price (or manner of calculation) and conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;
- voting rights, if any, of the preferred stock;
- preemptive rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;

- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon the liquidation, dissolution or winding up of our affairs;

- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the class or series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and

- any other specific terms, preferences, rights, limitations or restrictions of the preferred stock.

Our board of directors could authorize the issuance of shares of preferred stock with terms and conditions that could have the effect of discouraging a takeover or other transaction that might involve a premium price for holders of the shares or which holders might believe to be in their best interests. The issuance of preferred stock could adversely affect the voting power, conversion or other rights of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation.

The laws of the state of Delaware, the state of our incorporation, provide that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of such preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT (the ***"Agreement"),*** dated as of April 23, 2019 (the ***"Effective Date"),*** by and between ZIOPHARM Oncology, Inc., a Delaware corporation, with principal offices at One First Avenue, Parris Building, #34 Navy Yard Plaza, Boston, Massachusetts 02129 (the ***"Company"),*** and Jill Buck, presently residing at 84 Sunset Rock Rd., Andover, MA 01810 (the ***"Employee").***

WITNESSETH:

WHEREAS, the Company currently employs Employee as its Executive Vice President, GM Gene Therapy, pursuant to the terms of an Offer Letter dated September 1, 2015 and that certain Severance Agreement dated September 23, 2015 (collectively, the ***"Prior Employment Agreements");***

WHEREAS, the Company desires to continue employing Employee as Executive Vice President, GM Gene Therapy of the Company, and Employee desires to continue serving the Company in that capacity, upon the terms and subject to the conditions contained in this Agreement.

WHEREAS, the Company and Employee have mutually agreed that, as of the Effective Date, this Agreement shall amend, restate and replace the Prior Employment Agreements;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto agree as follows:

1)Employment.

a) Services. Employee will be employed by the Company as its Executive Vice President, GM Gene Therapy on the terms set forth herein. Employee will report to the Chief Executive Officer of the Company. Employee shall have such duties, authorities and responsibilities as are assigned by the Chief Executive Officer (or his or her designee) and as generally required of an Executive Vice President, GM Gene Therapy in companies that are substantially similar to the Company (collectively the ***"Services").*** Notwithstanding the foregoing, the Company may expand, reduce or otherwise alter the duties of Employee in its sole discretion; *provided, however,* that any such reduction or alteration of Employee's duties may constitute ***"Good Reason"*** for Employee's resignation (as such term is defined in Section 8(d) hereof), thereby potentially entitling Employee to the severance and other benefits provided pursuant to Section 9 of this Agreement. Employee agrees to perform her duties faithfully, to use her best efforts to advance the best interests of the Company, to devote substantially all of her business time, attention and energies to the business of the Company, and while she remains employed, not to engage in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage, that will interfere with the performance by Employee of her duties hereunder or that will adversely affect, or reflect negatively upon, the Company; *provided, however,* that Employee may engage in

the following activities to the extent that such activities, individually or collectively, do not interfere with the performance of Employee's duties and responsibilities hereunder: (A) participating in charitable, civic, educational, professional, community or industry affairs; (B) attending to personal financial matters; and (C) engaging in such other activities, subject to the prior written approval of the Company's Chief Executive Officer.

b) Acceptance. Employee hereby accepts such employment and agrees to render the Services.

c) Termination of Prior Employment Agreement. Effective as of 11:59 p.m. on the day immediately prior to the Effective Date, the Prior Employment Agreements shall automatically terminate and be of no further force and effect.

2)Employment is At-Will.

Employee acknowledges that this Agreement does not create any obligation on Employee's part to work for the Company, or on the part of the Company to employ Employee, for any fixed period of time. Employment is at-will and may be terminated at any time with or without ***"Cause"*** (as defined below) and without providing a reason for such termination.

3)Best Efforts; Place of Performance.

a) Employee shall devote substantially all of her business time, attention and energies to the business and affairs of the Company and shall use her best efforts to advance the best interests of the Company. Except as otherwise noted in this Agreement, during her employment with the Company, Employee shall not, without the prior written consent of the Company, accept other employment, perform services (including consulting services) for any other person or entity, or otherwise be actively engaged in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage.

b) The duties to be performed by Employee hereunder shall be performed primarily at the Company's offices in Boston, Massachusetts, subject to reasonable travel requirements on behalf of the Company.

4)Compensation. As full compensation for the performance by Employee of her duties under this Agreement, the Company shall pay Employee as follows:

a) Base Salary. The Company shall pay Employee a salary (as may be increased from time-to-time, the ***"Base Salary")*** equal to $350,000 per annum, which Base Salary shall be subject to review by the Company's Board of Directors (the ***"Board")*** or the Compensation Committee thereof at least annually, provided that the Base Salary shall not be subject to reduction except as contemplated by Section 8(d)(iii) below. Payment shall be made in accordance with the regular payroll practices of the Company in effect from time to time.

b) Discretionary Bonuses. Employee shall be eligible to receive an annual, discretionary performance-based bonus (the ***"Discretionary Performance Bonus"),*** based on Employee's performance as determined in its sole discretion by the Board or the Compensation Committee thereof for each calendar year. The target amount of the Discretionary Performance Bonus shall

be equal to forty percent (40%) of Employee's Base Salary, with the amount of the actual Discretionary Performance Bonus payable for each year determined by the Board or Compensation Committee in its sole discretion. The amount so determined shall be payable within 30 days following December 31 of each calendar year during Employee's employment under this Agreement; provided that Employee remains employed by the Company through December 31 of the calendar year during which the Discretionary Performance Bonus was earned. At the sole discretion of the Board, Employee may receive additional bonuses (each, an ***"Additional Discretionary Bonus")*** based upon her performance on behalf of the Company and/or the Company's performance. An Additional Discretionary Bonus, if any, shall be payable either as a lump-sum payment or in installments, in such amounts, in such manner and at such times as may be determined by the Board in its sole discretion.

c) Withholding. The Company shall withhold all applicable federal, state and local taxes and social security and such other amounts as may be required by law from all amounts and benefits payable or provided to Employee under this Agreement.

d) Expenses. The Company shall reimburse Employee for all normal, usual and necessary expenses incurred by Employee in furtherance of the business and affairs of the Company, including reasonable travel and entertainment expenses. The Company shall reimburse Employee upon timely receipt by the Company of appropriate vouchers or other proof of Employee's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company. The Company's expense reimbursement policy generally requires that application for reimbursement be made as soon as practicable after the expense is incurred, but in no event more than one year after the date of the expense. Reimbursements are made by the Company no less frequently than monthly, and for compliance with Code Section 409A (as hereinafter defined), not later than December 31 of the year following the year in which the expense was incurred.

e) Vacation and Other Benefits. Employee shall be entitled to a vacation equal to the greater of (i) four (4) weeks per annum (or pro rata portion thereof for any partial year), and (ii) the number of weeks of vacation Employee would be entitled to receive under the Company's policies, in addition to holidays observed by the Company as they fall on scheduled days of work. Vacation shall accrue, and be carried forward into the next year of employment, in accordance with the terms and conditions of the Company's generally applicable vacation policy. Notwithstanding anything to the contrary set forth in Section 9 of this Agreement or elsewhere in this Agreement, upon any termination of Employee's employment, the Company will provide timely payment to Employee in respect of any then accrued but unused vacation. Employee shall also be entitled to the rights and benefits for which she shall be eligible under any benefit or other plans (including, without limitation, dental, medical, medical reimbursement and hospital plans, pension plans, employee stock purchase plans, profit sharing plans, bonus plans and other so-called "***fringe"*** benefits) as the Company shall make available to other employees generally from time to time.

5)Confidentiality; Non-Compete. Employee acknowledges and affirms her compliance with the Invention, Non-Disclosure and Non-Competition Agreement, which she signed on September 23, 2015 (the ***"Non-Disclosure Agreement")*** and remains a condition of employment.

6)Assignment. Neither this Agreement nor any of the rights and obligations of Employee under this Agreement may be assigned, transferred or otherwise disposed of by Employee. Company may assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of Company's business or that aspect of Company's business in which Employee is principally involved.

7)Termination. Employee's employment hereunder may be terminated at any time, with or without Cause, and without providing a reason for such termination. This Agreement shall terminate upon termination of Employee's employment, except that the provisions of Sections 8 and 9 below shall survive any termination of this Agreement. The provisions of the Non-Disclosure Agreement shall survive termination of this Agreement.

8)Termination. Employee's employment hereunder shall be terminated upon Employee's death and may be terminated as follows:

a) Employee's employment hereunder may be terminated by the Company for Cause. Any of the following actions by the Employee or conditions shall constitute *"Cause":*

i) The willful or negligent failure, disregard or refusal by Employee to perform her duties hereunder for a period of thirty (30) calendar days after Employee has been given written notice thereof;

ii) Any act by Employee, that in the reasonable opinion of a majority of the Board has the effect of materially injuring the business or reputation of the Company or any of its affiliates;

iii) Misconduct by Employee in respect of the duties or obligations of Employee under this Agreement, including, without limitation, insubordination with respect to lawful directions received by Employee from the Company for a period of thirty (30) calendar days after Employee has been given written notice thereof;

iv) Employee's conviction of any felony or a misdemeanor involving moral turpitude (including entry of a nolo contendere plea);

v) The determination by the Company, after a reasonable and good faith investigation, following a written allegation by another employee of the Company, that Employee engaged in any conduct prohibited by law (including, without limitation, harassment that constitutes age, sex or race discrimination);

vi) Any misappropriation or embezzlement of the property of the Company or its affiliates (whether or not constituting a misdemeanor or felony);

vii) Material breach by Employee of any of the provisions of the Non-Disclosure Agreement, as determined by the Company in good faith; and viii) Failure by Employee to cure any breach in any material respect by Employee of any provision of this Agreement within thirty (30) calendar days after Employee has been given written notice thereof.

b) Employee's employment hereunder may be terminated by the Company due to Employee's Disability. For purposes of this Agreement, a termination for *"Disability"* shall occur upon rendering of a written termination notice by the Company after Employee has been unable to substantially perform her duties hereunder for 90 or more consecutive days, or more than 120 days in any consecutive 12-month period, by reason of any physical or mental illness or injury. For purposes of this Section 8(b), Employee agrees to make herself available and to cooperate in any reasonable examination by a reputable independent physician retained by the Company.

c) Employee's employment hereunder may be terminated by the Company (or its successor) upon the occurrence of a Change of Control. For purposes of this Agreement, ***"Change of Control"*** means (i) the acquisition, directly or indirectly, following the date hereof by any person (as such term is defined in Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended), in one transaction or a series of related transactions, of securities of the Company representing in excess of fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities if such person (or his or her or its affiliate(s)) does not own in excess of 50% of such voting power on the date of this Agreement, or (ii) the future disposition by the Company (whether direct or indirect, by sale of assets or stock, merger, consolidation or otherwise) of all or substantially all of its assets in one transaction or series of related transactions (other than (A) a merger effected exclusively for the purpose of changing the domicile of the Company, (B) financing activities in the ordinary course in which the Company sells its equity securities, or (C) a transfer to a person or entity that, immediately after the transfer, is or is controlled by a person or entity that controlled the Company before the transfer, within the meaning of Section 1.409A-3(i)(5)(vii)(B) of the Treasury regulations (the ***"Treasury Regulations")*** promulgated under Section 409A of the Internal Revenue Code of 1986, as amended ***("Code Section 409A").***

d) Employee's employment hereunder may be terminated by the Employee for Good Reason, provided that such termination occurs within six (6) months following the Employee becoming aware of the occurrence of an event of Good Reason (as defined below) and provided, further, that the Employee has provided the Company with written notice of an event of Good Reason within thirty (30) calendar days following the date Employee becomes aware of its occurrence and the Company shall have failed to cure the event of Good Reason within thirty (30) calendar days following the Company's receipt of such notice from Employee. For purposes of this Agreement, ***"Good Reason"*** shall mean any of the following: (i) the assignment to the Employee of duties that constitute a material diminution ***in*** Employee's authorities, duties, responsibilities, titles or offices as described herein; (ii) any material reduction by the Company of the Employee's authorities, duties, responsibilities, titles or offices; (iii) a reduction by the Company of greater than ten percent (10%) of the Employee's base compensation payable

hereunder, unless in connection with an across-the-board reduction of similar magnitude affecting similarly situated executives; (iv) the relocation of Employee's principal place of employment, without Employee's consent, in a manner that lengthens his one-way commute distance by fifty (50) or more miles from his then-current principal place of employment immediately prior to such relocation; or (v) a material breach by the Company of this Agreement.

9)Compensation upon Termination.

a) If Employee's employment is terminated as a result of her death or Disability, as a result of her voluntary resignation other than for Good Reason, or by the Company for Cause, the Company shall pay to Employee or to the Employee's estate, as applicable, her accrued Base Salary through the date of termination and expense reimbursement amounts for expenses incurred through the date of termination. Employee shall have no further entitlement to any other compensation or benefits from the Company, except as provided in Section 10(a) below regarding continuation of insurance coverage. Employee shall not be entitled to any bonus payable after the date of termination, except where Employee remains employed by the Company through December 31 of the calendar year during which the Discretionary Performance Bonus was earned as provided in Section 4(b) above.

b) If Employee's employment is terminated by the Company without Cause, and other than by reason of death or Disability, or if the Employee's employment is terminated by the Employee for Good Reason, then the Company shall pay to Employee her Base Salary through the date of her termination and any expense reimbursement amounts for expenses incurred through the date of termination. In addition, if (i) Employee has executed and delivered to the Company, within sixty (60) days after the effective date of that termination, a written general release in a form satisfactory to the Company, whereby Employee shall release the Company from any and all potential liabilities arising out of Employee's employment with, or termination from employment from, the Company (a ***"Release");*** and (ii) the rescission period specified in that release has expired, the Company shall pay to Employee a severance amount equal to nine (9) months of Employee's then current Base Salary (the ***"Severance"),*** less applicable withholdings and deductions, which amount shall be payable in a single lump sum on or before the 90th day after the effective date of that termination; provided that the Board may, upon written notice to Employee, reduce the Severance amount to six (6) months of Employee's then current Base Salary in the event the Company enters bankruptcy or insolvency proceedings. For purposes of the calculation of the Severance and any payment of the Discretionary Performance Bonus target amount pursuant to Section 9(c), Employee's Base Salary and Discretionary Performance Bonus target amounts shall be calculated without giving effect to any reduction that would give rise to Employee's right to resign for Good Reason.

c) If (i) Employee's employment is terminated by the Company (or its successor) without Cause or the Employee resigns for Good Reason, in either case (A) within eighteen (18) months following the occurrence of a Change of Control or (B) within 90 days prior to and in connection with the occurrence of a Change of Control, then in addition to the severance benefits provided under Section 9(b) above and conditioned upon both the execution and non-revocation of the Release and the execution of a new agreement containing post-termination restrictive covenants (including, without limitation, a non-competition covenant) of the same scope, duration and terms as the Non-Disclosure Agreement, (1) all unvested options or restricted stock awards (collectively,

"Unvested Stock Awards") held by Employee at the time that such termination occurs shall be accelerated and deemed to have vested as of the termination date; and (2) the Company shall pay Employee the target amount of the Discretionary Performance Bonus contemplated by Section 4(b) (i.e., forty percent (40%) of Employee's Base Salary) that would have been payable for the calendar year in which termination of her employment occurs, payable in a single lump sum on the 90th day after the effective date of termination. Prior to any Change of Control, the Company shall take such action as may be necessary to amend the terms of any Unvested Stock Award (either granted prior to or after the Effective Date) in order to provide the acceleration contemplated by this Section 9(c).

d) This Section 9 sets forth the only obligations of the Company with respect to the termination of the Employee's employment with the Company, and the Employee acknowledges that, upon the termination of her employment, she shall not be entitled to any payments or benefits which are not explicitly provided in Section 9.

e) Amounts payable to Employee pursuant to Sections 9(b) or 9(c) hereof shall only be paid following Employee's separation from service with the Company. The time for payment of amounts due following Employee's separation from service pursuant to this Section 9 shall be determined in accordance with the Company's regular payroll and bonus payment practices, subject to the provisions of Code Section 409A and the Treasury Regulations. Notwithstanding anything herein to the contrary, (i) if at the time of Employee's termination of employment with the Company the Company's common stock is publicly traded (as determined under Code Section 409A), (ii) Employee is a ***"specified employee"*** (as determined under Code Section 409A), and the deferral of the commencement of any payments or benefits otherwise payable hereunder as a result of such termination of employment is necessary in order to prevent any accelerated or additional tax under Code Section 409A, then the Company will defer the commencement of the payment of any such payments or benefits hereunder (without any reduction in such payments or benefits ultimately paid or provided to Employee) until the date that is six (6) months and one day following Employee's termination of employment with the Company (or the earliest date as is permitted under Code Section 409A without any accelerated or additional tax); and (ii) if any other payments of money or other benefits due to Employee hereunder could cause the application of an accelerated or additional tax under Code Section 409A, then such payments or other benefits shall be deferred if deferral will make such payment or other benefits compliant under Code Section 409A, or otherwise such payment or other benefits shall be restructured, to the extent possible, in a manner, determined by the Board, that is reasonably expected not to cause such an accelerated or additional tax. For purposes of Code Section 409A, each payment made under this Agreement shall be designated as a ***"separate payment"*** within the meaning of the Code Section 409A, and, to the extent required by Code Section 409A, references herein to Employee's ***"termination of employment"*** shall refer to Employee's ***"separation from service"*** (within the meaning of Code Section 409A) with the Company (as defined to include any affiliates required to be taken into account for that definition of separation from service). To the extent any reimbursements or in-kind benefits due to Employee under this Agreement constitute ***"deferred compensation"*** under Code Section 409A, any such reimbursements or in-kind benefits shall be paid to Employee in a manner consistent with Section 1.409A-3(i)(1)(iv) of the Treasury Regulations. The compensation (including without limitation separation benefits) provisions of this Agreement shall be interpreted, operated and administered in a manner intended to comply with any applicable

requirements of Code Section 409A, the Treasury Regulations, and subsequent guidance issued under Code Section 409A.

10)Effect of Termination on Benefits.

a) If Employee's employment with the Company is terminated, and pursuant to the Consolidated Omnibus Budget Reconciliation Act ***("COBRA"),*** Employee may elect to continue her existing medical, vision and/or dental coverage under the Company's group health insurance plans, and the entire cost of any associated insurance premiums shall be borne entirely by Employee; provided, however, that if Employee's employment is terminated by the Company without Cause or the Employee resigns for Good Reason, the Company shall pay its contributions for such medical and dental insurance coverage (the ***"COBRA Premium Benefits")*** for the first nine (9) months following the date of termination (the ***"COBRA Payment Period");*** provided that the Board may, upon written notice to Employee, reduce the COBRA Payment Period to six months in the event the Company enters bankruptcy or insolvency proceedings.

b) Notwithstanding anything to the contrary set forth in Section 10(a), if the Company determines, in its sole discretion, that the Company cannot provide the COBRA Premium Benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Employee a taxable cash amount, which payment shall be made regardless of whether the Employee or her qualifying family members elect COBRA continuation coverage (the ***"Health Care Benefit Payment").*** The Health Care Benefit Payment shall be paid in installments on the same schedule that the COBRA Premium Benefits would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA Premium Benefits, and shall be paid until the expiration of the COBRA Payment Period.

c) Except as otherwise specifically provided for in subsection (a) or (b) of this Section 10, or in Section 9 above, upon termination of Employee's employment, Employee shall have no further entitlement to any other compensation or benefits from the Company.

11)Application of Internal Revenue Code Section 280G.

a) If any payment or benefit Employee would receive pursuant to a Change of Control from the Company or otherwise ***("Payment")*** would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the ***"Excise Tax"),*** then such Payment shall be equal to the Reduced Amount. The ***"Reduced Amount"*** shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in

the manner that results in the greatest economic benefit for Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

b) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Employee agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Employee will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

c) Unless Employee and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change of Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change of Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

d) The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Employee and the Company within fifteen (15) calendar days after the date on which Employee's right to a Payment is triggered (if requested at that time by Employee or the Company) or such other time as requested by Employee or the Company.

12)Miscellaneous.

a) All amounts payable hereunder are intended to be either exempt from Code Section 409A or be subject to and comply with Code Section 409A. At all times all provisions of this Agreement shall be construed in a manner consistent with the foregoing.

b) This Agreement, together with the Non-Disclosure Agreement, constitutes the entire agreement and understanding between the Company and Employee concerning the subject matter hereof and supersedes any previous agreement, oral, written or otherwise, between the Company and Employee concerning the subject matter hereof, including but not limited to the Prior Employment Agreements. No modification, amendment, termination or waiver of this Agreement shall be binding unless in writing and signed by a duly authorized officer of the Company.

c) Employee represents that: (i) neither the execution or delivery of this Agreement nor the performance by Employee of her duties and other obligations hereunder violate or will violate any statute, law, determination or award, or conflict with or constitute a default or breach of any covenant or obligation under (whether immediately, upon the giving of notice or lapse of time or both) any prior employment agreement, contract, or other instrument to which Employee is a party or by which she is bound; (ii) Employee will not disclose to the Company any confidential or proprietary information of any other person or employer and will not bring to the Company any property or documents of a confidential nature that belong to any other person or employer; and (iii) Employee does not have in her possession any property belonging to another employer, whether in paper or electronic format.

d) Employee represents that she has the full right, power and legal capacity to enter and deliver this Agreement and to perform her duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of Employee enforceable against her in accordance with its terms. No approvals or consent of any person or entities are required for Employee to execute and deliver this Agreement or perform her duties and other obligations hereunder.

e) Employee understands, acknowledges and agrees that any violation by Employee of any of the terms of this Agreement may result in Employee's immediate termination.

f) The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and such terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party.

g) This Agreement shall be construed, interpreted, and applied in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of law provisions. Employee agrees all disputes arising hereunder shall be adjudicated only and exclusively in the state and federal courts of Massachusetts, and Employee hereby consents to the personal jurisdiction and venue of such courts. The Company and Employee each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

h) In the event any provision of this Agreement shall be held to be void, unlawful or unenforceable, all of the remaining provisions shall nevertheless remain in full force and effect.

i) All notices, requests, consents and other communications, required or permitted to be given hereunder, shall be in writing and shall be delivered personally, by an overnight courier service or sent by registered or certified mail, postage prepaid, return receipt requested, to the parties at the addresses set forth on the first page of this Agreement, and shall be deemed given when so delivered personally or by overnight courier, or, if mailed, when deposited in the United States mail. Either party may designate another address, for receipt of notices hereunder by giving notice to the other party in accordance with this paragraph (h).

j) The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

k) This Agreement may be executed in any number of counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument.

l) Employee hereby acknowledges receipt of a duplicate copy of this Agreement. EMPLOYEE ACKNOWLEDGES THAT BEFORE SIGNING EMPLOYEE HAS READ THIS AGREEMENT AND UNDERSTANDS ITS TERMS AND CONDITIONS.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement under seal as of the date first above written.

EMPLOYEE:

/s/ Jill Buck
Jill Buck
Date:

ZIOPHARM Oncology, Inc.

/s/ Laurence Cooper
By: Laurence Cooper
Title: Chief Executive Officer
Date:

Exhibit 10.18

AMENDMENT TO EMPLOYMENT AGREEMENT

AMENDMENT TO EMPLOYMENT AGREEMENT (the ***"Amendment"***), dated as of November 23, 2020 (the "***Effective Date***"), by and between ZIOPHARM Oncology, Inc., a Delaware corporation (the ***"Company"***), and Jill Buck (the ***"Employee"***). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Employment Agreement (as defined below).

W I T N E S S E T H:

WHEREAS, the Company currently employs Employee as its Executive Vice President, General Manager Gene Therapy, pursuant to the terms that certain Employment Agreement dated April 23, 2019 (the "***Employment Agreement***");

WHEREAS, the Company and Employee desire to amend the terms of the Employment Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto agree as follows:

1) Amendment to Compensation upon Termination. Section 9(b) of the Employment Agreement is deleted in its entirely and replaced with the following:

> "b) If Employee's employment is terminated by the Company without Cause, and other than by reason of death or Disability, or if the Employee's employment is terminated by the Employee for Good Reason, then the Company shall pay to Employee her Base Salary through the date of her termination and any expense reimbursement amounts for expenses incurred through the date of termination. In addition, if (i) Employee has executed and delivered to the Company, within sixty (60) days after the effective date of that termination, a written general release in a form satisfactory to the Company, whereby Employee shall release the Company from any and all potential liabilities arising out of Employee's employment with, or termination from employment from, the Company (a "***Release***"); and (ii) the rescission period specified in that release has expired, the Company shall pay to Employee a severance amount equal to twelve (12) months of Employee's then current Base Salary (the ***"Severance"***), less applicable withholdings and deductions, which amount shall be payable in a single lump sum on or before the 90th day after the effective date of that termination. For purposes of the calculation of the Severance and any payment of the Discretionary Performance Bonus target amount pursuant to Section 9(c), Employee's Base Salary and Discretionary Performance Bonus target amounts shall be calculated without giving effect to any reduction that would give rise to Employee's right to resign for Good Reason."

2) Amendment to Effect of Termination on Benefits. Section 10(a) of the Employment Agreement is deleted in its entirely and replaced with the following:

"a) If Employee's employment with the Company is terminated, and pursuant to the Consolidated Omnibus Budget Reconciliation Act ("***COBRA***"), Employee may elect to continue her existing medical, vision and/or dental coverage under the Company's group health insurance plans, and the entire cost of any associated insurance premiums shall be borne entirely by Employee; provided, however, that if Employee's employment is terminated by the Company without Cause or the Employee resigns for Good Reason, the Company shall pay its contributions for such medical and dental insurance coverage (the ***"COBRA Premium Benefits***") for the first twelve (12) months following the date of termination (the "***COBRA Payment Period***")."

3) Miscellaneous. This Amendment shall not amend or modify the covenants, terms, conditions, rights and obligations of the parties hereto under the Employment Agreement, except as specifically set forth herein. The Employment Agreement shall continue in full force and effect in accordance with its terms as amended by this Amendment. This Amendment shall be construed, interpreted, and applied in accordance with the laws of the Commonwealth of Massachusetts. This Amendment may be executed in any number of counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument.

[***Remainder of page intentionally left blank; signature page follows***]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment under seal as of the date first above written.

EMPLOYEE:

/s/ Jill Buck
Jill Buck

ZIOPHARM Oncology, Inc.:

/s/ Laurence Cooper
By: Laurence Cooper
Title: Chief Executive Officer

Exhibit 10.19

EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT (the ***"Agreement"),*** dated as of April 23, 2019 (the ***"Effective Date"),*** by and between ZIOPHARM Oncology, Inc., a Delaware corporation, with principal offices at One First Avenue, Parris Building, #34 Navy Yard Plaza, Boston, Massachusetts 02129 (the ***"Company"),*** and Eleanor De Groot, presently residing at 3722 Sunset Blvd, Houston, TX 77005 (the ***"Employee").***

WITNESSETH:

WHEREAS, the Company currently employs Employee as its Executive Vice President, General Manager Cell Therapy, pursuant to the terms of an Offer Letter dated June 22, 2015 and that certain Severance Agreement dated July 13, 2015 (collectively, the ***"Prior Employment Agreements");***

WHEREAS, the Company desires to continue employing Employee as Executive Vice President, General Manager Cell Therapy of the Company, and Employee desires to continue serving the Company **in** that capacity, upon the terms and subject to the conditions contained in this Agreement.

WHEREAS, the Company and Employee have mutually agreed that, as of the Effective Date, this Agreement shall amend, restate and replace the Prior Employment Agreements;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto agree as follows:

1)Employment.

a) Services. Employee will be employed by the Company as its Executive Vice President, General Manager Cell Therapy on the terms set forth herein. Employee will report to the Chief Executive Officer of the Company. Employee shall have such duties, authorities and responsibilities as are assigned by the Chief Executive Officer (or his or her designee) and as generally required of a Executive Vice President, General Manager Cell Therapy in companies that are substantially similar to the Company (collectively the ***"Services").*** Notwithstanding the foregoing, the Company may expand, reduce or otherwise alter the duties of Employee in its sole discretion; *provided, however,* that any such reduction or alteration of Employee's duties may constitute ***"Good Reason"*** for Employee's resignation (as such term is defined in Section 8(d) hereof), thereby potentially entitling Employee to the severance and other benefits provided pursuant to Section 9 of this Agreement. Employee agrees to perform her duties faithfully, to use her best efforts to advance the best interests of the Company, to devote substantially all of her business time, attention and energies to the business of the Company, and while she remains employed, not to engage in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage, that will interfere with the performance by Employee of her duties hereunder or that will adversely affect, or reflect negatively upon, the Company; *provided, however,* that Employee may engage in the following activities to the extent

that such activities, individually or collectively, do not interfere with the performance of Employee's duties and responsibilities hereunder: (A) participating in charitable, civic, educational, professional, community or industry affairs; (B) attending to personal financial matters; and (C) engaging in such other activities, subject to the prior written approval of the Company's Chief Executive Officer.

b) Acceptance. Employee hereby accepts such employment and agrees to render the Services.

c) Termination of Prior Employment Agreement. Effective as of 11:59 p.m. on the day immediately prior to the Effective Date, the Prior Employment Agreements shall automatically terminate and be of no further force and effect.

2)Employment is At-Will.

Employee acknowledges that this Agreement does not create any obligation on Employee's part to work for the Company, or on the part of the Company to employ Employee, for any fixed period of time. Employment is at-will and may be terminated at any time with or without ***"Cause"*** (as defined below) and without providing a reason for such termination.

3)Best Efforts; Place of Performance.

a) Employee shall devote substantially all of her business time, attention and energies to the business and affairs of the Company and shall use her best efforts to advance the best interests of the Company. Except as otherwise noted in this Agreement, during her employment with the Company, Employee shall not, without the prior written consent of the Company, accept other employment, perform services (including consulting services) for any other person or entity, or otherwise be actively engaged in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage.

b) The duties to be performed by Employee hereunder shall be performed primarily at the Company's offices in Houston, Texas, subject to reasonable travel requirements on behalf of the Company.

4)Compensation. As full compensation for the performance by Employee of her duties under this Agreement, **the** Company shall pay Employee as follows:

a) Base Salary. The Company shall pay Employee a salary (as may be increased from time-to-time, the ***"Base Salary")*** equal to $350,000 per annum, which Base Salary shall be subject to review by the Company's Board of Directors (the ***"Board")*** or the Compensation Committee thereof at least annually, provided that the Base Salary shall not be subject to reduction except as contemplated by Section 8(d)(iii) below. Payment **shall be** made in accordance with the regular payroll practices of the Company in effect from time to time.

b) Discretionary Bonuses. Employee shall be eligible to receive an annual, discretionary performance-based bonus (the ***"Discretionary Performance Bonus"),*** based on Employee's performance as determined in its sole discretion by the Board or the Compensation Committee thereof for each calendar year. The target amount of the Discretionary Performance Bonus shall

be equal to forty percent (40%) of Employee's Base Salary, with the amount of the actual Discretionary Performance Bonus payable for each year determined by the Board or Compensation Committee in its sole discretion. The amount so determined shall be payable within 30 days following December 31 of each calendar year during Employee's employment under this Agreement; provided that Employee remains employed by the Company through December 31 of the calendar year during which the Discretionary Performance Bonus was earned. At the sole discretion of the Board, Employee may receive additional bonuses (each, an ***"Additional Discretionary Bonus")*** based upon her performance on behalf of the Company and/or the Company's performance. An Additional Discretionary Bonus, if any, shall be payable either as a lump-sum payment or in installments, in such amounts, in such manner and at such times as may be determined by the Board in its sole discretion.

c) Withholding. The Company shall withhold all applicable federal, state and local taxes and social security and such other amounts as may be required by law from all amounts and benefits payable or provided to Employee under this Agreement.

d) Expenses. The Company shall reimburse Employee for all normal, usual and necessary expenses incurred by Employee in furtherance of the business and affairs of the Company, including reasonable travel and entertainment expenses. The Company shall reimburse Employee upon timely receipt by the Company of appropriate vouchers or other proof of Employee's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company. The Company's expense reimbursement policy generally requires that application for reimbursement be made as soon as practicable after the expense is incurred, but in no event more than one year after the date of the expense. Reimbursements are made by the Company no less frequently than monthly, and for compliance with Code Section 409A (as hereinafter defined), not later than December 31 of the year following the year in which the expense was incurred.

e) Vacation and Other Benefits. Employee shall be entitled to a vacation equal to the greater of (i) four (4) weeks per annum (or pro rata portion thereof for any partial year), and (ii) the number of weeks of vacation Employee would be entitled to receive under the Company's policies, in addition to holidays observed by the Company as they fall on scheduled days of work. Vacation shall accrue, and be carried forward into the next year of employment, in accordance with the terms and conditions of the Company's generally applicable vacation policy. Notwithstanding anything to the contrary set forth in Section 9 of this Agreement or elsewhere in this Agreement, upon any termination of Employee's employment, the Company will provide timely payment to Employee in respect of any then accrued but unused vacation. Employee shall also be entitled to the rights and benefits for which she shall be eligible under any benefit or other plans (including, without limitation, dental, medical, medical reimbursement and hospital plans, pension plans, employee stock purchase plans, profit sharing plans, bonus plans and other so-called ***"fringe"*** benefits) as the Company shall make available to other employees generally from time to time.

5)Confidentiality; Non-Compete. Employee acknowledges and affirms her compliance with the Invention, Non-Disclosure and Non-Competition Agreement, which she signed on June 29, 2015 (the ***"Non-Disclosure Agreement")*** and remains a condition of employment.

6)Assignment. Neither this Agreement nor any of the rights and obligations of Employee under this Agreement may be assigned, transferred or otherwise disposed of by Employee. Company may assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of Company's business or that aspect of Company's business in which Employee is principally involved.

7)Termination. Employee's employment hereunder may be terminated at any time, with or without Cause, and without providing a reason for such termination. This Agreement shall terminate upon termination of Employee's employment, except that the provisions of Sections 8 and 9 below shall survive any termination of this Agreement. The provisions of the Non-Disclosure Agreement shall survive termination of this Agreement.

8)Termination. Employee's employment hereunder shall be terminated upon Employee's death and may be terminated as follows:

a) Employee's employment hereunder may be terminated by the Company for Cause. Any of the following actions by the Employee or conditions shall constitute ***"Cause":***

i) The willful or negligent failure, disregard or refusal by Employee to perform her duties hereunder for a period of thirty (30) calendar days after Employee has been given written notice thereof;

ii) Any act by Employee, that in the reasonable opinion of a majority of the Board has the effect of materially injuring the business or reputation of the Company or any of its affiliates;

iii) Misconduct by Employee in respect of the duties or obligations of Employee under this Agreement, including, without limitation, insubordination with respect to lawful directions received by Employee from the Company for a period of thirty (30) calendar days after Employee has been given written notice thereof;

iv) Employee's conviction of any felony or a misdemeanor involving moral turpitude (including entry of a nolo contendere plea);

v) The determination by the Company, after a reasonable and good faith investigation, following a written allegation by another employee of the Company, that Employee engaged in any conduct prohibited by law (including, without limitation, harassment that constitutes age, sex or race discrimination);

vi) Any misappropriation or embezzlement of the property of the Company or its affiliates (whether or not constituting a misdemeanor or felony);

vii) Material breach by Employee of any of the provisions of the Non-Disclosure Agreement, as determined by the Company in good faith; and

viii) Failure by Employee to cure any breach in any material respect by Employee of any provision of this Agreement within thirty (30) calendar days after Employee has been given written notice thereof

b) Employee's employment hereunder may be terminated by the Company due to Employee's Disability. For purposes of this Agreement, a termination for ***"Disability"*** shall occur upon rendering of a written termination notice by the Company after Employee has been unable to substantially perform her duties hereunder for 90 or more consecutive days, or more than 120 days in any consecutive 12-month period, by reason of any physical or mental illness or injury. For purposes of this Section 8(b), Employee agrees to make herself available and to cooperate in any reasonable examination by a reputable independent physician retained by the Company.

c) Employee's employment hereunder may be terminated by the Company (or its successor) upon the occurrence of a Change of Control. For purposes of this Agreement, ***"Change of Control"*** means (i) the acquisition, directly or indirectly, following the date hereof by any person (as such term is defined in Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended), in one transaction or a series of related transactions, of securities of the Company representing in excess of fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities if such person (or his or her or its affiliate(s)) does not own in excess of 50% of such voting power on the date of this Agreement, or (ii) the future disposition by the Company (whether direct or indirect, by sale of assets or stock, merger, consolidation or otherwise) of all or substantially all of its assets in one transaction or series of related transactions (other than (A) a merger effected exclusively for the purpose of changing the domicile of the Company, (B) financing activities in the ordinary course in which the Company sells its equity securities, or (C) a transfer to a person or entity that, immediately after the transfer, is or is controlled by a person or entity that controlled the Company before the transfer, within the meaning of Section 1.409A-3(i)(5)(vii)(B) of the Treasury regulations (the ***"Treasury Regulations")*** promulgated under Section 409A of the Internal Revenue Code of 1986, as amended ***("Code Section 409A").***

d) Employee's employment hereunder may be terminated by the Employee for Good Reason, provided that such termination occurs within six (6) months following the Employee becoming aware of the occurrence of an event of Good Reason (as defined below) and provided, further, that the Employee has provided the Company with written notice of an event of Good Reason within thirty (30) calendar days following the date Employee becomes aware of its occurrence and the Company shall have failed to cure the event of Good Reason within thirty (30) calendar days following the Company's receipt of such notice from Employee. For purposes of this Agreement, ***"Good Reason"*** shall mean any of the following: (i) the assignment to the Employee of duties that constitute a material diminution in Employee's authorities, duties, responsibilities, titles or offices as described herein; (ii) any material reduction by the Company of the Employee's authorities, duties, responsibilities, titles or offices; (iii) a reduction by the Company of greater than ten percent (10%) of the Employee's base compensation payable hereunder, unless in connection with an across-the-board reduction of similar magnitude affecting similarly situated executives; (iv) the relocation of Employee's principal place of employment,

without Employee's consent, in a manner that lengthens his one-way commute distance by fifty (50) or more miles from his then-current principal place of employment immediately prior to such relocation; or (v) a material breach by the Company of this Agreement.

9)<u>Compensation upon Termination</u>.

a) If Employee's employment is terminated as a result of her death or Disability, as a result of her voluntary resignation other than for Good Reason, or by the Company for Cause, the Company shall pay to Employee or to the Employee's estate, as applicable, her accrued Base Salary through the date of termination and expense reimbursement amounts for expenses incurred through the date of termination. Employee shall have no further entitlement to any other compensation or benefits from the Company, except as provided in Section 10(a) below regarding continuation of insurance coverage. Employee shall not be entitled to any bonus payable after the date of termination, except where Employee remains employed by the Company through December 31 of the calendar year during which the Discretionary Performance Bonus was earned as provided in Section 4(b) above.

b) If Employee's employment is terminated by the Company without Cause, and other than by reason of death or Disability, or if the Employee's employment is terminated by the Employee for Good Reason, then the Company shall pay to Employee her Base Salary through the date of her termination and any expense reimbursement amounts for expenses incurred through the date of termination. In addition, if (i) Employee has executed and delivered to the Company, within sixty (60) days after the effective date of that termination, a written general release in a form satisfactory to the Company, whereby Employee shall release the Company from any and all potential liabilities arising out of Employee's employment with, or termination from employment from, the Company (a ***"Release");*** and (ii) the rescission period specified in that release has expired, the Company shall pay to Employee a severance amount equal to nine (9) months of Employee's then current Base Salary (the ***"Severance"),*** less applicable withholdings and deductions, which amount shall be payable in a single lump sum on or before the 90th day after the effective date of that termination; provided that the Board may, upon written notice to Employee, reduce the Severance amount to six (6) months of Employee's then current Base Salary in the event the Company enters bankruptcy or insolvency proceedings. For purposes of the calculation of the Severance and any payment of the Discretionary Performance Bonus target amount pursuant to Section 9(c), Employee's Base Salary and Discretionary Performance Bonus target amounts shall be calculated without giving effect to any reduction that would give rise to Employee's right to resign for Good Reason.

If (i) Employee's employment is terminated by the Company (or its successor) without Cause or the Employee resigns for Good Reason, in either case (A) within eighteen (18) months following the occurrence of a Change of Control or (B) within 90 days prior to and in connection with the occurrence of a Change of Control, then in addition to the severance benefits provided under Section 9(b) above and conditioned upon both the execution and non-revocation of the Release and the execution of a new agreement containing post-termination restrictive covenants (including, without limitation, a non-competition covenant) of the same scope, duration and terms as the Non-Disclosure Agreement, (1) all unvested options or restricted stock awards (collectively, ***"Unvested Stock Awards")*** held by Employee at the time that such termination occurs shall be accelerated and deemed to have vested as of the

termination date; and (2) the Company shall pay Employee the target amount of the Discretionary Performance Bonus contemplated by Section 4(b) (i.e., forty percent (40%) of Employee's Base Salary) that would have been payable for the calendar year in which termination of her employment occurs, payable in a single lump sum on the 90th day after the effective date of termination. Prior to any Change of Control, the Company shall take such action as may be necessary to amend the terms of any Unvested Stock Award (either granted prior to or after the Effective Date) in order to provide the acceleration contemplated by this Section 9(c).

c) This Section 9 sets forth the only obligations of the Company with respect to the termination of the Employee's employment with the Company, and the Employee acknowledges that, upon the termination of her employment, she shall not be entitled to any payments or benefits which are not explicitly provided in Section 9.

d) Amounts payable to Employee pursuant to Sections 9(b) or 9(c) hereof shall only be paid following Employee's separation from service with the Company. The time for payment of amounts due following Employee's separation from service pursuant to this Section 9 shall be determined in accordance with the Company's regular payroll and bonus payment practices, subject to the provisions of Code Section 409A and the Treasury Regulations. Notwithstanding anything herein to the contrary, (i) if at the time of Employee's termination of employment with the Company the Company's common stock is publicly traded (as determined under Code Section 409A), (ii) Employee is a ***"specified employee"*** (as determined under Code Section 409A), and the deferral of the commencement of any payments or benefits otherwise payable hereunder as a result of such termination of employment is necessary in order to prevent any accelerated or additional tax under Code Section 409A, then the Company will defer the commencement of the payment of any such payments or benefits hereunder (without any reduction in such payments or benefits ultimately paid or provided to Employee) until the date that is six (6) months and one day following Employee's termination of employment with the Company (or the earliest date as is permitted under Code Section 409A without any accelerated or additional tax); and (ii) if any other payments of money or other benefits due to Employee hereunder could cause the application of an accelerated or additional tax under Code Section 409A, then such payments or other benefits shall be deferred if deferral will make such payment or other benefits compliant under Code Section 409A, or otherwise such payment or other benefits shall be restructured, to the extent possible, in a manner, determined by the Board, that is reasonably expected not to cause such an accelerated or additional tax. For purposes of Code Section 409A, each payment made under this Agreement shall be designated as a ***"separate payment"*** within the meaning of the Code Section 409A, and, to the extent required by Code Section 409A, references herein to Employee's ***"termination of employment"*** shall refer to Employee's ***"separation from service"*** (within the meaning of Code Section 409A) with the Company (as defined to include any affiliates required to be taken into account for that definition of separation from service). To the extent any reimbursements or in-kind benefits due to Employee under this Agreement constitute ***"deferred compensation"*** under Code Section 409A, any such reimbursements or in-kind benefits shall be paid to Employee in a manner consistent with Section 1.409A-3(i)(1)(iv) of the Treasury Regulations. The compensation (including without limitation separation benefits) provisions of this Agreement shall be interpreted, operated and administered in a manner intended to comply with any applicable requirements of Code Section 409A, the Treasury Regulations, and subsequent guidance issued under Code Section 409A.

10)Effect of Termination on Benefits.

a) If Employee's employment with the Company is terminated, and pursuant to the Consolidated Omnibus Budget Reconciliation Act ***("COBRA"),*** Employee may elect to continue her existing medical, vision and/or dental coverage under the Company's group health insurance plans, and the entire cost of any associated insurance premiums shall be borne entirely by Employee; provided, however, that if Employee's employment is terminated by the Company without Cause or the Employee resigns for Good Reason, the Company shall pay its contributions for such medical and dental insurance coverage (the ***"COBRA Premium Benefits")*** for the first nine (9) months following the date of termination (the ***"COBRA Payment Period");*** provided that the Board may, upon written notice to Employee, reduce the COBRA Payment Period to six (6) months in the event the Company enters bankruptcy or insolvency proceedings.

b) Notwithstanding anything to the contrary set forth in Section 10(a), if the Company determines, in its sole discretion, that the Company cannot provide the COBRA Premium Benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Employee a taxable cash amount, which payment shall be made regardless of whether the Employee or her qualifying family members elect COBRA continuation coverage (the ***"Health Care Benefit Payment").*** The Health Care Benefit Payment shall be paid in installments on the same schedule that the COBRA Premium Benefits would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA Premium Benefits, and shall be paid until the expiration of the COBRA Payment Period.

c) Except as otherwise specifically provided for in subsection (a) or (b) of this Section 10, or in Section 9 above, upon termination of Employee's employment, Employee shall have no further entitlement to any other compensation or benefits from the Company.

11)Application of Internal Revenue Code Section 280G.

a) If any payment or benefit Employee would receive pursuant to a Change of Control from the Company or otherwise ***("Payment")*** would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the ***"Excise Tax"),*** then such Payment shall be equal to the Reduced Amount. The ***"Reduced Amount"*** shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

b) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Employee agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Employee will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

c) Unless Employee and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change of Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change of Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

d) The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Employee and the Company within fifteen (15) calendar days after the date on which Employee's right **to** a Payment is triggered (if requested at that time by Employee or the Company) or such other time as requested by Employee or the Company.

12)Miscellaneous.

a) All amounts payable hereunder are intended to be either exempt from Code Section 409A or be subject to and comply with Code Section 409A. At all times all provisions of this Agreement shall be construed in a manner consistent with the foregoing.

b) This Agreement, together with the Non-Disclosure Agreement, constitutes the entire agreement and understanding between the Company and Employee concerning the subject matter hereof and supersedes any previous agreement, oral, written or otherwise, between the Company and Employee concerning the subject matter hereof, including but not limited to the Prior Employment Agreements. No modification, amendment, termination or waiver of this Agreement shall be binding unless in writing and signed by a duly authorized officer of the Company.

c) Employee represents that: (i) neither the execution or delivery of this Agreement nor the performance by Employee of her duties and other obligations hereunder violate or will violate any statute, law, determination or award, or conflict with or constitute a default or breach of any covenant or obligation under (whether immediately, upon the giving of notice or lapse of time or both) any prior employment agreement, contract, or other instrument to which Employee is a party or by which she is bound; (ii) Employee will not disclose to the Company any confidential or proprietary information of any other person or employer and will not bring to the Company any property or documents of a confidential nature that belong to any other person or employer; and (iii) Employee does not have in her possession any property belonging to another employer, whether in paper or electronic format.

d) Employee represents that she has the full right, power and legal capacity to enter and deliver this Agreement and to perform her duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of Employee enforceable against her in accordance with its terms. No approvals or consent of any person or entities are required for Employee to execute and deliver this Agreement or perform her duties and other obligations hereunder.

e) Employee understands, acknowledges and agrees that any violation by Employee of any of the terms of this Agreement may result in Employee's immediate termination.

f) The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and such terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party.

g) This Agreement shall be construed, interpreted, and applied in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of law provisions. Employee agrees all disputes arising hereunder shall be adjudicated only and exclusively in the state and federal courts of Massachusetts, and Employee hereby consents to the personal jurisdiction and venue of such courts. The Company and Employee each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

h) In the event any provision of this Agreement shall be held to be void, unlawful or unenforceable, all of the remaining provisions shall nevertheless remain in full force and effect.

i) All notices, requests, consents and other communications, required or permitted to be given hereunder, shall be in writing and shall be delivered personally, by an overnight courier service or sent by registered or certified mail, postage prepaid, return receipt requested, to the parties at the addresses set forth on the first page of this Agreement, and shall be deemed given when so delivered personally or by overnight courier, or, if mailed, when deposited in the United States mail. Either party may designate another address, for receipt of notices hereunder by giving notice to the other party in accordance with this paragraph (h).

j) The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

k) This Agreement may be executed in any number of counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument.

l) Employee hereby acknowledges receipt of a duplicate copy of this Agreement. EMPLOYEE ACKNOWLEDGES THAT BEFORE SIGNING EMPLOYEE HAS READ THIS AGREEMENT AND UNDERSTANDS ITS TERMS AND CONDITIONS.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement under seal as of the date first above written.

EMPLOYEE:

/s/ Eleanor De Groot
Eleanor De Groot
Date: 23 April 2019

ZIOPHARM Oncology, Inc.:

/s/ Laurence Cooper
By: Laurence Cooper
Title: Chief Executive Officer
Date:

Exhibit 10.20

AMENDMENT TO EMPLOYMENT AGREEMENT

AMENDMENT TO EMPLOYMENT AGREEMENT (the ***"Amendment"***), dated as of November 23, 2020 (the "***Effective Date***"), by and between ZIOPHARM Oncology, Inc., a Delaware corporation (the ***"Company"***), and Eleanor De Groot (the ***"Employee"***). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Employment Agreement (as defined below).

W I T N E S S E T H:

WHEREAS, the Company currently employs Employee as its Executive Vice President, General Manager Cell Therapy, pursuant to the terms that certain Employment Agreement dated April 23, 2019 (the "***Employment Agreement***");

WHEREAS, the Company and Employee desire to amend the terms of the Employment Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto agree as follows:

1) Amendment to Compensation upon Termination. Section 9(b) of the Employment Agreement is deleted in its entirely and replaced with the following:

> "b) If Employee's employment is terminated by the Company without Cause, and other than by reason of death or Disability, or if the Employee's employment is terminated by the Employee for Good Reason, then the Company shall pay to Employee her Base Salary through the date of her termination and any expense reimbursement amounts for expenses incurred through the date of termination. In addition, if (i) Employee has executed and delivered to the Company, within sixty (60) days after the effective date of that termination, a written general release in a form satisfactory to the Company, whereby Employee shall release the Company from any and all potential liabilities arising out of Employee's employment with, or termination from employment from, the Company (a "***Release***"); and (ii) the rescission period specified in that release has expired, the Company shall pay to Employee a severance amount equal to twelve (12) months of Employee's then current Base Salary (the ***"Severance"***), less applicable withholdings and deductions, which amount shall be payable in a single lump sum on or before the 90th day after the effective date of that termination. For purposes of the calculation of the Severance and any payment of the Discretionary Performance Bonus target amount pursuant to Section 9(c), Employee's Base Salary and Discretionary Performance Bonus target amounts shall be calculated without giving effect to any reduction that would give rise to Employee's right to resign for Good Reason."

2) <u>Amendment to Effect of Termination on Benefits</u>. Section 10(a) of the Employment Agreement is deleted in its entirely and replaced with the following:

> "a) If Employee's employment with the Company is terminated, and pursuant to the Consolidated Omnibus Budget Reconciliation Act ("***COBRA***"), Employee may elect to continue her existing medical, vision and/or dental coverage under the Company's group health insurance plans, and the entire cost of any associated insurance premiums shall be borne entirely by Employee; provided, however, that if Employee's employment is terminated by the Company without Cause or the Employee resigns for Good Reason, the Company shall pay its contributions for such medical and dental insurance coverage (the ***"COBRA Premium Benefits***") for the first twelve (12) months following the date of termination (the "***COBRA Payment Period***")."

3) <u>Miscellaneous</u>. This Amendment shall not amend or modify the covenants, terms, conditions, rights and obligations of the parties hereto under the Employment Agreement, except as specifically set forth herein. The Employment Agreement shall continue in full force and effect in accordance with its terms as amended by this Amendment. This Amendment shall be construed, interpreted, and applied in accordance with the laws of the Commonwealth of Massachusetts. This Amendment may be executed in any number of counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument.

[***Remainder of page intentionally left blank; signature page follows***]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement under seal as of the date first above written.

EMPLOYEE:

/s/ Eleanor De Groot
Eleanor De Groot

ZIOPHARM Oncology, Inc.:

/s/ Laurence Cooper
By: Laurence Cooper
Title: Chief Executive Officer

EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT (the ***"Agreement"***), dated as of September 30, 2020 (the "***Effective Date***"), by and between ZIOPHARM Oncology, Inc., a Delaware corporation, with principal offices at One First Avenue, Parris Building, #34 Navy Yard Plaza, Boston, Massachusetts 02129 (the ***"Company"***), and Raffaele Baffa, M.D., Ph.D., presently residing at 28 Cliff Rd, Wellesley, MA 02481 (the ***"Employee"***).

W I T N E S S E T H:

WHEREAS, the Company desires to employ Employee as Executive Vice President, Chief Medical Officer of the Company, and Employee desires to serve the Company in that capacity, upon the terms and subject to the conditions contained in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto agree as follows:

1) Employment.

a) Services. Employee will be employed by the Company as its Executive Vice President, Chief Medical Officer starting November 15, 2020 (the "***Start Date***"), on the terms set forth herein. Employee will report to the Chief Executive Officer of the Company. Employee shall have such duties, authorities and responsibilities as are assigned by the Chief Executive Officer (or his or her designee) and as generally required of an Executive Vice President, Chief Medical Officer in companies that are substantially similar to the Company (collectively the ***"Services"***). Notwithstanding the foregoing, the Company may expand, reduce or otherwise alter the duties of Employee in its sole discretion; *provided*, *however*, that any such reduction or alteration of Employee's duties may constitute ***"Good Reason"*** for Employee's resignation (as such term is defined in Section 8(d) hereof), thereby potentially entitling Employee to the severance and other benefits provided pursuant to Section 9 of this Agreement. Employee agrees to perform his duties faithfully, to use his best efforts to advance the best interests of the Company, to devote substantially all of his business time, attention and energies to the business of the Company, and while he remains employed, not to engage in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage, that will interfere with the performance by Employee of his duties hereunder or that will adversely affect, or reflect negatively upon, the Company; *provided*, *however*, that Employee may engage in the following activities to the extent that such activities, individually or collectively, do not interfere with the performance of Employee's duties and responsibilities hereunder: (A) participating in charitable, civic, educational, professional, community or industry affairs; (B) attending to personal financial matters; and (C) engaging in such other activities, subject to the prior written approval of the Company's Chief Executive Officer.

b) Acceptance. Employee hereby accepts such employment and agrees to render the Services.

2) Employment is At-Will.

Employee acknowledges that this Agreement does not create any obligation on Employee's part to work for the Company, or on the part of the Company to employ Employee, for any fixed period of time. Employment is at-will and may be terminated at any time with or without "***Cause***" (as defined below) and without providing a reason for such termination.

3) Best Efforts; Place of Performance.

a) Employee shall devote substantially all of his business time, attention and energies to the business and affairs of the Company and shall use his best efforts to advance the best interests of the Company. Except as otherwise noted in this Agreement, during his employment with the Company, Employee shall not, without the prior written consent of the Company, accept other employment, perform services (including consulting services) for any other person or entity, or otherwise be actively engaged in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage.

b) The duties to be performed by Employee hereunder shall be performed primarily at the Company's offices in Boston, Massachusetts, subject to reasonable travel requirements on behalf of the Company.

4) Compensation. As full compensation for the performance by Employee of his duties under this Agreement, the Company shall pay Employee as follows:

a) Base Salary. The Company shall pay Employee a salary (as may be increased from time-to-time, the ***"Base Salary"***) equal to $465,000 per annum ($19,375.00 per pay period), which Base Salary shall be subject to review by the Company's Board of Directors (the "***Board***") or the Compensation Committee thereof at least annually, provided that the Base Salary shall not be subject to reduction except as contemplated by Section 8(d)(iii) below. Payment shall be made in accordance with the regular payroll practices of the Company in effect from time to time.

b) Discretionary Bonuses. Employee shall be eligible to receive an annual, discretionary performance-based bonus (the ***"Discretionary Performance Bonus"***), based on Employee's performance as determined in its sole discretion by the Board or the Compensation Committee thereof for each calendar year. The target amount of the Discretionary Performance Bonus shall be equal to forty percent (40%) of Employee's Base Salary, with the amount of the actual Discretionary Performance Bonus payable for each year determined by the Board or Compensation Committee in its sole discretion. The amount so determined shall be payable within 30 days following December 31 of each calendar year during Employee's employment under this Agreement; provided that Employee remains employed by the Company through December 31 of the calendar year during which the Discretionary Performance Bonus was earned. The amount of Discretionary Performance Bonus for fiscal 2020, if any, may be determined on a pro rata based on the number of days in such calendar year on which the Employee was employed by the Company. At the sole discretion of the Board, Employee may receive additional bonuses (each, an ***"Additional Discretionary Bonus"***) based upon his performance on behalf of the Company and/or the Company's performance. An Additional Discretionary Bonus, if any, shall be payable either as a lump-sum payment or in installments, in such amounts, in such manner and at such times as may be determined by the Board in its sole discretion.

c) Sign-On Bonus. On the Start Date, the Company will pay Employee a one-time sign-on bonus of $160,000 (the "***Sign-on Bonus***"). In the event that Employee's employment is terminated by the Company for Cause or Employee resigns without Good Reason, in either case, prior to the one-year anniversary of the Start Date, then Employee will promptly repay the entire Sign-on Bonus to the Company. In the event that Employee's employment is terminated by the Company for Cause or Employee resigns without Good Reason, in either case, on or after the one-year anniversary of the Start Date but prior to the second-year anniversary of the Start Date, then Employee will promptly repay one-half of the Sign-on Bonus to the Company.

d) Stock Option. As a material inducement to Employee's acceptance of the Company's offer to employ Employee, subject to approval by the Board, the Company is pleased to offer Employee an option (the "***Option***") to purchase 500,000 shares of common stock of the Company, with an exercise price equal to the fair market value of a share of common stock as of the date of grant. The Option will vest with respect to 25% of the shares underlying the Option on the one-year anniversary of the Start Date and the remaining 75% of the shares underlying the Option will vest in equal quarterly installments over the three-year period following the one-year anniversary of the Start Date, subject to Employee's continued service with the Company through each relevant vesting date. This option grant shall be subject to the terms and conditions of the Company's 2020 Equity Incentive Plan and a Stock Option Agreement. No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant confer any right to continue vesting or employment.

e) Restricted Stock. Subject to approval by the Board, the Company will grant Employee an award of 200,000 shares of restricted common stock of the Company (the "***Restricted Stock***"). The Restricted Stock shall vest in four (4) equal annual installments on the anniversary of the Start Date, subject to Employee's continued service with the Company through each relevant vesting date. Upon the termination of Employee's employment, the Company shall have a right to reacquire all or any part of the Restricted Stock that have not vested by the date of such termination. Such Restricted Stock grant will be governed by the Company's 2020 Equity Incentive Plan and the standard form of Restricted Stock Agreement, which agreement shall be entered into by Employee as a condition to the grant of the Restricted Stock.

f) Withholding. The Company shall withhold all applicable federal, state and local taxes and social security and such other amounts as may be required by law from all amounts and benefits payable or provided to Employee under this Agreement.

g) Expenses. The Company shall reimburse Employee for all normal, usual and necessary expenses incurred by Employee in furtherance of the business and affairs of the Company, including reasonable travel and entertainment expenses. The Company shall reimburse Employee upon timely receipt by the Company of appropriate vouchers or other proof of Employee's expenditures and otherwise in accordance with any expense reimbursement policy as may from time to time be adopted by the Company. The Company's expense reimbursement policy generally requires that application for reimbursement be made as soon as practicable after the expense is incurred, but in no event more than one year after the date of the expense. Reimbursements are made by the Company no less frequently than monthly, and for compliance with Code Section 409A (as hereinafter defined), not later than December 31 of the year following the year in which the expense was incurred.

h) Vacation and Other Benefits. Employee shall be entitled to a vacation equal to the greater of (i) four (4) weeks per annum (or pro rata portion thereof for any partial year), and (ii) the number of weeks of vacation Employee would be entitled to receive under the Company's policies, in addition to holidays observed by the Company as they fall on scheduled days of work. Vacation shall accrue, and be carried forward into the next year of employment, in accordance with the terms and conditions of the Company's generally applicable vacation policy. Notwithstanding anything to the contrary set forth in Section 9 of this Agreement or elsewhere in this Agreement, upon any termination of Employee's employment, the Company will provide timely payment to Employee in respect of any then accrued but unused vacation. Employee shall also be entitled to the rights and benefits for which he shall be eligible under any benefit or other plans (including, without limitation, dental, medical, medical reimbursement and hospital plans, pension plans, employee stock purchase plans, profit sharing plans, bonus plans and other so-called "***fringe***" benefits) as the Company shall make available to other employees generally from time to time.

5) **Confidentiality; Non-Compete.** Employee acknowledges that all Company employees, including Employee, are required to sign the Invention, Non-Disclosure and Non-Competition Agreement in the form attached hereto and incorporated herein as Exhibit A (the "***Non-Disclosure Agreement***") as a condition of employment. If Employee declines to sign the Non-Disclosure Agreement on or prior to the commencement of his employment hereunder, this Agreement shall be terminated and be of no further force and effect, ab initio, and no amount of Base Salary, severance or other compensation or payment shall be due Employee hereunder.

6) **Assignment.** Neither this Agreement nor any of the rights and obligations of Employee under this Agreement may be assigned, transferred or otherwise disposed of by Employee. Company may assign its rights and obligations hereunder to any person or entity that succeeds to all or substantially all of Company's business or that aspect of Company's business in which Employee is principally involved.

7) **Termination.** Employee's employment hereunder may be terminated at any time, with or without Cause, and without providing a reason for such termination. This Agreement shall terminate upon termination of Employee's employment, except that the provisions of Sections 8 and 9 below shall survive any termination of this Agreement. The provisions of the Non-Disclosure Agreement shall survive termination of this Agreement.

8) **Termination.** Employee's employment hereunder shall be terminated upon Employee's death and may be terminated as follows:

a) Employee's employment hereunder may be terminated by the Company for Cause. Any of the following actions by the Employee or conditions shall constitute ***"Cause"***:

i) The willful or negligent failure, disregard or refusal by Employee to perform his duties hereunder for a period of thirty (30) calendar days after Employee has been given written notice thereof;

ii) Any act by Employee, that in the reasonable opinion of a majority of the Board has the effect of materially injuring the business or reputation of the Company or any of its affiliates;

iii) Misconduct by Employee in respect of the duties or obligations of Employee under this Agreement, including, without limitation, insubordination with respect to lawful directions received by Employee from the Company for a period of thirty (30) calendar days after Employee has been given written notice thereof;

iv) Employee's conviction of any felony or a misdemeanor involving moral turpitude (including entry of a nolo contendere plea);

v) The determination by the Company, after a reasonable and good faith investigation, following a written allegation by another employee of the Company, that Employee engaged in any conduct prohibited by law (including, without limitation, harassment that constitutes age, sex or race discrimination);

vi) Any misappropriation or embezzlement of the property of the Company or its affiliates (whether or not constituting a misdemeanor or felony);

vii) Material breach by Employee of any of the provisions of the Non-Disclosure Agreement, as determined by the Company in good faith; and

viii) Failure by Employee to cure any breach in any material respect by Employee of any provision of this Agreement within thirty (30) calendar days after Employee has been given written notice thereof.

b) Employee's employment hereunder may be terminated by the Company due to Employee's Disability. For purposes of this Agreement, a termination for ***"Disability"*** shall occur upon rendering of a written termination notice by the Company after Employee has been unable to substantially perform his duties hereunder for 90 or more consecutive days, or more than 120 days in any consecutive 12-month period, by reason of any physical or mental illness or injury. For purposes of this Section 8(b), Employee agrees to make himself available and to cooperate in any reasonable examination by a reputable independent physician retained by the Company.

c) Employee's employment hereunder may be terminated by the Company (or its successor) upon the occurrence of a Change of Control. For purposes of this Agreement, ***"Change of Control"*** means (i) the acquisition, directly or indirectly, following the date hereof by any person (as such term is defined in Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934, as amended), in one transaction or a series of related transactions, of securities of the Company representing in excess of fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities if such person (or his or her or its affiliate(s)) does not own in excess of 50% of such voting power on the date of this Agreement, or (ii) the future disposition by the Company (whether direct or indirect, by sale of assets or stock, merger, consolidation or otherwise) of all or substantially all of its assets in one transaction or series of related transactions (other than (A) a merger effected exclusively for the purpose of changing the domicile of the Company, (B) financing activities in the ordinary course in which the Company sells its equity securities, or (C) a transfer to a person or entity that, immediately after the transfer, is or is controlled by a person or entity that controlled the Company before the transfer, within the meaning of Section 1.409A-3(i)(5)(vii)(B) of the Treasury regulations (the ***"Treasury Regulations"***) promulgated under Section 409A of the Internal Revenue Code of 1986, as amended (***"Code Section 409A"***).

d) Employee's employment hereunder may be terminated by the Employee for Good Reason, provided that such termination occurs within six (6) months following the Employee becoming aware of the occurrence of an event of Good Reason (as defined below) and provided, further, that the Employee has provided the Company with written notice of an event of Good Reason within thirty (30) calendar days following the date Employee becomes aware of its

occurrence and the Company shall have failed to cure the event of Good Reason within thirty (30) calendar days following the Company's receipt of such notice from Employee. For purposes of this Agreement, ***"Good Reason"*** shall mean any of the following: (i) the assignment to the Employee of duties that constitute a material diminution in Employee's authorities, duties, responsibilities, titles or offices as described herein; (ii) any material reduction by the Company of the Employee's authorities, duties, responsibilities, titles or offices; (iii) a reduction by the Company of greater than ten percent (10%) of the Employee's base compensation payable hereunder, unless in connection with an across-the-board reduction of similar magnitude affecting similarly situated executives; (iv) the relocation of Employee's principal place of employment, without Employee's consent, in a manner that lengthens his one-way commute distance by fifty (50) or more miles from his then-current principal place of employment immediately prior to such relocation; or (v) a material breach by the Company of this Agreement.

9) <u>Compensation upon Termination</u>.

a) If Employee's employment is terminated as a result of his death or Disability, as a result of his voluntary resignation other than for Good Reason, or by the Company for Cause, the Company shall pay to Employee or to the Employee's estate, as applicable, his accrued Base Salary through the date of termination and expense reimbursement amounts for expenses incurred through the date of termination. Employee shall have no further entitlement to any other compensation or benefits from the Company, except as provided in Section 10(a) below regarding continuation of insurance coverage. Employee shall not be entitled to any bonus payable after the date of termination, except where Employee remains employed by the Company through December 31 of the calendar year during which the Discretionary Performance Bonus was earned as provided in Section 4(b) above.

b) If Employee's employment is terminated by the Company without Cause, and other than by reason of death or Disability, or if the Employee's employment is terminated by the Employee for Good Reason, then the Company shall pay to Employee his Base Salary through the date of his termination and any expense reimbursement amounts for expenses incurred through the date of termination. In addition, if (i) Employee has executed and delivered to the Company, within sixty (60) days after the effective date of that termination, a written general release in a form satisfactory to the Company, whereby Employee shall release the Company from any and all potential liabilities arising out of Employee's employment with, or termination from employment from, the Company (a "***Release***"); and (ii) the rescission period specified in that release has expired, the Company shall pay to Employee a severance amount equal to nine (9) months of Employee's then current Base Salary (the ***"Severance"***), less applicable withholdings and deductions, which amount shall be payable in a single lump sum on or before the 90th day after the effective date of that termination; provided that the Board may, upon written notice to Employee, reduce the Severance amount to six (6) months of Employee's then current Base Salary in the event the Company enters bankruptcy or insolvency proceedings. For purposes of the calculation of the Severance and any payment of the Discretionary Performance Bonus target amount pursuant to Section 9(c), Employee's Base Salary and Discretionary Performance Bonus target amounts shall be calculated without giving effect to any reduction that would give rise to Employee's right to resign for Good Reason.

c) If (i) Employee's employment is terminated by the Company (or its successor) without Cause or the Employee resigns for Good Reason, in either case (A) within eighteen (18) months following the occurrence of a Change of Control or (B) within 90 days prior to and in connection with the occurrence of a Change of Control, then in addition to the severance benefits provided under Section 9(b) above and conditioned upon both the execution and non-revocation of the Release and the execution of a new agreement containing post-termination restrictive covenants (including, without limitation, a non-competition covenant) of the same scope, duration and terms as the Non-Disclosure Agreement, (1) all unvested options or restricted stock awards (collectively, "***Unvested Stock Awards***") held by Employee at the time that such termination occurs shall be accelerated and deemed to have vested as of the termination date; and (2) the Company shall pay Employee the target amount of the Discretionary Performance Bonus contemplated by Section 4(b) (i.e., forty percent (40%) of Employee's Base Salary) that would have been payable for the calendar year in which termination of his employment occurs, payable in a single lump sum on the 90th day after the effective date of termination. Prior to any Change of Control, the Company shall take such action as may be necessary to amend the terms of any Unvested Stock Award (either granted prior to or after the Effective Date) in order to provide the acceleration contemplated by this Section 9(c).

d) This Section 9 sets forth the only obligations of the Company with respect to the termination of the Employee's employment with the Company, and the Employee acknowledges that, upon the termination of his employment, he shall not be entitled to any payments or benefits which are not explicitly provided in Section 9.

e) Amounts payable to Employee pursuant to Sections 9(b) or 9(c) hereof shall only be paid following Employee's separation from service with the Company. The time for payment of amounts due following Employee's separation from service pursuant to this Section 9 shall be determined in accordance with the Company's regular payroll and bonus payment practices, subject to the provisions of Code Section 409A and the Treasury Regulations. Notwithstanding anything herein to the contrary, (i) if at the time of Employee's termination of employment with the Company the Company's common stock is publicly traded (as determined under Code Section 409A), (ii) Employee is a ***"specified employee"*** (as determined under Code Section 409A), and the deferral of the commencement of any payments or benefits otherwise payable hereunder as a result of such termination of employment is necessary in order to prevent any accelerated or additional tax under Code Section 409A, then the Company will defer the commencement of the payment of any such payments or benefits hereunder (without any reduction in such payments or benefits ultimately paid or provided to Employee) until the date that is six (6) months and one day following Employee's termination of employment with the Company (or the earliest date as is permitted under Code Section 409A without any accelerated or additional tax); and (ii) if any other payments of money or other benefits due to Employee hereunder could cause the application of an accelerated or additional tax under Code Section 409A, then such payments or other benefits shall be deferred if deferral will make such payment or other benefits compliant under Code Section 409A, or otherwise such payment or other benefits shall be restructured, to the extent possible, in a manner, determined by the Board, that is reasonably expected not to cause such an accelerated or additional tax. For purposes of Code Section 409A, each payment made under this Agreement shall be designated as a ***"separate payment"*** within the meaning of the Code Section 409A, and, to the extent required by Code Section 409A, references herein to Employee's ***"termination of employment"*** shall refer to Employee's ***"separation from service"*** (within the meaning of Code

Section 409A) with the Company (as defined to include any affiliates required to be taken into account for that definition of separation from service). To the extent any reimbursements or in-kind benefits due to Employee under this Agreement constitute ***"deferred compensation"*** under Code Section 409A, any such reimbursements or in-kind benefits shall be paid to Employee in a manner consistent with Section 1.409A-3(i)(1)(iv) of the Treasury Regulations. The compensation (including without limitation separation benefits) provisions of this Agreement shall be interpreted, operated and administered in a manner intended to comply with any applicable requirements of Code Section 409A, the Treasury Regulations, and subsequent guidance issued under Code Section 409A.

10) Effect of Termination on Benefits.

a) If Employee's employment with the Company is terminated, and pursuant to the Consolidated Omnibus Budget Reconciliation Act ("***COBRA***"), Employee may elect to continue his existing medical, vision and/or dental coverage under the Company's group health insurance plans, and the entire cost of any associated insurance premiums shall be borne entirely by Employee; provided, however, that if Employee's employment is terminated by the Company without Cause or the Employee resigns for Good Reason, the Company shall pay its contributions for such medical and dental insurance coverage (the ***"COBRA Premium Benefits***") for the first nine (9) months following the date of termination (the "***COBRA Payment Period***"); provided that the Board may, upon written notice to Employee, reduce the COBRA Payment Period to six (6) months in the event the Company enters bankruptcy or insolvency proceedings.

b) Notwithstanding anything to the contrary set forth in Section 10(a), if the Company determines, in its sole discretion, that the Company cannot provide the COBRA Premium Benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof pay Employee a taxable cash amount, which payment shall be made regardless of whether the Employee or his qualifying family members elect COBRA continuation coverage (the "***Health Care Benefit Payment***"). The Health Care Benefit Payment shall be paid in installments on the same schedule that the COBRA Premium Benefits would otherwise have been paid to the insurer. The Health Care Benefit Payment shall be equal to the amount that the Company otherwise would have paid for COBRA Premium Benefits, and shall be paid until the expiration of the COBRA Payment Period.

c) Except as otherwise specifically provided for in subsection (a) or (b) of this Section 10, or in Section 9 above, upon termination of Employee's employment, Employee shall have no further entitlement to any other compensation or benefits from the Company.

11) Application of Internal Revenue Code Section 280G.

a) If any payment or benefit Employee would receive pursuant to a Change of Control from the Company or otherwise (***"Payment"***) would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the ***"Excise Tax"***), then such Payment shall be equal to the Reduced Amount. The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest

portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

b) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Employee agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Employee will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

c) Unless Employee and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change of Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change of Control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

d) The Company shall use commercially reasonable efforts to cause the accounting firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Employee and the Company within fifteen (15) calendar days after the date on which Employee's right to a Payment is triggered (if requested at that time by Employee or the Company) or such other time as requested by Employee or the Company.

12) Miscellaneous.

a) All amounts payable hereunder are intended to be either exempt from Code Section 409A or be subject to and comply with Code Section 409A. At all times all provisions of this Agreement shall be construed in a manner consistent with the foregoing.

b) This Agreement, together with the Non-Disclosure Agreement, constitutes the entire agreement and understanding between the Company and Employee concerning the subject matter hereof and supersedes any previous agreement, oral, written or otherwise, between the Company and Employee concerning the subject matter hereof. No modification, amendment, termination or waiver of this Agreement shall be binding unless in writing and signed by a duly authorized officer of the Company.

c) Employee represents that: (i) neither the execution or delivery of this Agreement nor the performance by Employee of his duties and other obligations hereunder violate or will violate any statute, law, determination or award, or conflict with or constitute a default or breach of any covenant or obligation under (whether immediately, upon the giving of notice or lapse of time or both) any prior employment agreement, contract, or other instrument to which Employee is a party or by which he is bound; (ii) Employee will not disclose to the Company any confidential or proprietary information of any other person or employer and will not bring to the Company any property or documents of a confidential nature that belong to any other person or employer; and (iii) Employee does not have in his possession any property belonging to another employer, whether in paper or electronic format.

d) Employee represents that he has the full right, power and legal capacity to enter and deliver this Agreement and to perform his duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of Employee enforceable against him in accordance with its terms. No approvals or consent of any person or entities are required for Employee to execute and deliver this Agreement or perform his duties and other obligations hereunder.

e) Employee understands, acknowledges and agrees that any violation by Employee of any of the terms of this Agreement may result in Employee's immediate termination.

f) The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and such terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party.

g) This Agreement shall be construed, interpreted, and applied in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of law provisions. Employee agrees all disputes arising hereunder shall be adjudicated only and exclusively in the state and federal courts of Massachusetts, and Employee hereby consents to the personal jurisdiction and venue of such courts. The Company and Employee each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

h) In the event any provision of this Agreement shall be held to be void, unlawful or unenforceable, all of the remaining provisions shall nevertheless remain in full force and effect.

i) All notices, requests, consents and other communications, required or permitted to be given hereunder, shall be in writing and shall be delivered personally, by an overnight courier service or sent by registered or certified mail, postage prepaid, return receipt requested, to the parties at the addresses set forth on the first page of this Agreement, and shall be deemed given when so delivered personally or by overnight courier, or, if mailed, when deposited in the United States mail. Either party may designate another address, for receipt of notices hereunder by giving notice to the other party in accordance with this paragraph (h).

j) The section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

k) This Agreement may be executed in any number of counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument.

l) Employee hereby acknowledges receipt of a duplicate copy of this Agreement. EMPLOYEE ACKNOWLEDGES THAT BEFORE SIGNING EMPLOYEE HAS READ THIS AGREEMENT AND UNDERSTANDS ITS TERMS AND CONDITIONS.

[***Remainder of page intentionally left blank; signature page follows***]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement under seal as of the date first above written.

EMPLOYEE:

/s/ Raffaele Baffa

Raffaele Baffa, M.D., Ph.D.
Date: 9/30/2020

Ziopharm Oncology, Inc.:

/s/ Laurence Cooper

By: Laurence Cooper
Title: Chief Executive Officer
Date: 10/1/2020

Exhibit 10.22

AMENDMENT TO EMPLOYMENT AGREEMENT

AMENDMENT TO EMPLOYMENT AGREEMENT (the ***"Amendment"***), dated as of November 23, 2020 (the "***Effective Date***"), by and between ZIOPHARM Oncology, Inc., a Delaware corporation (the ***"Company"***), and Raffaele Baffa, M.D., Ph.D. (the ***"Employee"***). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Employment Agreement (as defined below).

W I T N E S E T H:

WHEREAS, the Company currently employs Employee as its Chief Medical Officer, pursuant to the terms that certain Employment Agreement dated September 30, 2020 (the "***Employment Agreement***");

WHEREAS, the Company and Employee desire to amend the terms of the Employment Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto agree as follows:

1) **Amendment to Compensation upon Termination.** Section 9(b) of the Employment Agreement is deleted in its entirely and replaced with the following:

"b) If Employee's employment is terminated by the Company without Cause, and other than by reason of death or Disability, or if the Employee's employment is terminated by the Employee for Good Reason, then the Company shall pay to Employee his Base Salary through the date of his termination and any expense reimbursement amounts for expenses incurred through the date of termination. In addition, if (i) Employee has executed and delivered to the Company, within sixty (60) days after the effective date of that termination, a written general release in a form satisfactory to the Company, whereby Employee shall release the Company from any and all potential liabilities arising out of Employee's employment with, or termination from employment from, the Company (a "***Release***"); and (ii) the rescission period specified in that release has expired, the Company shall pay to Employee a severance amount equal to twelve (12) months of Employee's then current Base Salary (the ***"Severance"***), less applicable withholdings and deductions, which amount shall be payable in a single lump sum on or before the 90th day after the effective date of that termination. For purposes of the calculation of the Severance and any payment of the Discretionary Performance Bonus target amount pursuant to Section 9(c), Employee's Base Salary and Discretionary Performance Bonus target amounts shall be calculated without giving effect to any reduction that would give rise to Employee's right to resign for Good Reason."

2) **Amendment to Effect of Termination on Benefits.** Section 10(a) of the Employment Agreement is deleted in its entirely and replaced with the following:

"a) If Employee's employment with the Company is terminated, and pursuant to the Consolidated Omnibus Budget Reconciliation Act ("***COBRA***"), Employee may elect to continue his existing medical, vision and/or dental coverage under the Company's group health insurance plans, and the entire cost of any associated insurance premiums shall be borne entirely by Employee; provided, however, that if Employee's employment is terminated by the Company without Cause or the Employee resigns for Good Reason, the Company shall pay its contributions for such medical and dental insurance coverage (the ***"COBRA Premium Benefits***") for the first twelve (12) months following the date of termination (the "***COBRA Payment Period***")."

3) **Miscellaneous.** This Amendment shall not amend or modify the covenants, terms, conditions, rights and obligations of the parties hereto under the Employment Agreement, except as specifically set forth herein. The Employment Agreement shall continue in full force and effect in accordance with its terms as amended by this Amendment. This Amendment shall be construed, interpreted, and applied in accordance with the laws of the Commonwealth of Massachusetts. This Amendment may be executed in any number of counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument.

[***Remainder of page intentionally left blank; signature page follows***]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment under seal as of the date first above written.

EMPLOYEE:

/s/ Raffaele Baffa
Raffaele Baffa

ZIOPHARM Oncology, Inc.:

/s/ Laurence Cooper
By: Laurence Cooper
Title: Chief Executive Officer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE ALAUNOS THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) IS CUSTOMARILY AND ACTUALLY TREATED AS PRIVATE.

PUBLIC HEALTH SERVICE

Amendment

This **Agreement** is based on the model Amendment Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the PHS within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by

National Cancer Institute

an Institute or Center (hereinafter referred to as the "**IC**") of the

NIH

and

Ziopharm Oncology, Inc., hereinafter referred to as the "**Licensee**",

having offices at One First Avenue, Parris Building #34, Navy Yard Plaza, Boston, MA 02129,

created and operating under the laws of Delaware.

Tax ID No.: 84-1475642

A-112-2021

THIRD AMENDMENT TO L-190-2019-0

This is the third amendment ("Third Amendment") of the agreement by and between the **IC** and **Licensee** having an effective date of May 28, 2019 and having IC Reference Number L-190-2019-0 ("**Agreement**"). This **Third Amendment**, having IC Reference Number L-190-2019-3 includes, in addition to the amendments made below, 1) a Signature Page, and 2) Attachment 1 (Royalty Payment Information).

WHEREAS, the **IC** and the **Licensee** desire that the **Agreement** be amended a third time as set forth below in order to modify and clarify certain terms of the **Agreement**.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, the **IC** and the Licensee, intending to be bound, hereby mutually agree to the following:

1) Paragraph 6.11 of the Agreement shall be deleted and replaced with the following:

The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon sixty (60) days written notice to the **IC** and owe no payment obligation under Paragraph 6.9 for patent-related expenses paid in that country after sixty (60) days of the effective date of the written notice.

For clarity, if the **Licensee** surrenders rights to any patent application of the **Licensed Patent Rights** in the **Licensed Territory** from which a child application is later filed (e.g., a divisional or continuation application), such child application shall, consistent with Paragraph 2.11, be considered a **Licensed Patent Right** as of the filing date and all rights and obligations with respect thereto apply.

Notwithstanding any other provisions of this Paragraph 6.11 of the **Agreement**, (a) the **Licensee** may elect to surrender all future child applications of a patent application of the **Licensed Patent Rights** in one or more jurisdictions of the **Licensed Territory**, prior to substantial efforts toward the preparation for filing of such child application(s) being made by the **IC**, and (b) the **Licensee** may surrender rights to a particular child application, prior to substantial efforts toward its preparation for filing being made by the **IC**, in each case (a) and (b), effective immediately upon written notice to the IC, and owe no payment obligation under Paragraph 6.9 for patent-related expenses paid for such child application(s) thereafter.

2) Paragraph 13.5 of the Agreement shall be deleted and replaced with the following:

The **IC** shall specifically have the right to terminate or modify, at its option, this Agreement by written notice to the **Licensee**, if the **IC** determines in good faith that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **IC's** reasonable

satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this Agreement that has not been remedied within the ninety (90) day period set forth in Paragraph 13.2 above;

(e) is not keeping the **Licensed Products** or the **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived; or

(g) has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under this **Agreement**.

3) Paragraph 13.6 of the Agreement shall be deleted and replaced with the following:

In making the determination referenced in Paragraph 13.5, the **IC** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **IC** shall give written notice to the **Licensee** providing the Licensee specific notice of, and a [***] day opportunity to respond to, the **IC's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **IC's** concerns as to the items referenced in 13.5(a)-13.5(g) within [***] days following written notice from the IC or fails to initiate corrective action to the IC's reasonable satisfaction, the IC may terminate this Agreement upon written notice to the Licensee.

4) Within sixty (60) days of the execution of this Third Amendment, the Licensee shall pay the IC an amendment issue royalty in the sum of two hundred fifty US Dollars ($250.00). Payment options may be found in Attachment 1.

5) In the event any provision(s) of the Agreement is/are inconsistent with Attachment 1, such provision(s) is/are hereby amended to the extent required to avoid such inconsistency and to give effect to the payment information in such Attachment 1.

6) All terms and conditions of the Agreement not herein amended remain binding and in effect.

7) The terms and conditions of this Third Amendment shall, at the IC's sole option, be considered by the IC to be withdrawn from the Licensee's consideration and the terms and conditions of this Third Amendment, and the Third Amendment itself, to be null and void, unless this Third Amendment is executed by the Licensee and a fully executed original is received by the IC within sixty (60) days from the date of the IC's signature found at the Signature Page.

8) This Third Amendment is effective upon execution by all parties.

SIGNATURES BEGIN ON NEXT PAGE

THIRD AMENDMENT TO L-190-2019/0

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Fifth Amendment** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the **IC**:

/s/ Richard U. Rodriguez — 4-9-21

Richard U. Rodriguez, MBA — Date
Associate Director
Technology Transfer Center
National Cancer Institute

National Institutes of Health Mailing Address or E-mail Address for **Agreement** notices and reports:

License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: [***]

For the **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

/s/ Richard U. Rodriguez — 4-16-2021

Signature of Authorized Official — Date

Name: Robert Hadfield
Title: General Counsel

A-112-2021

I. Official and Mailing Address for **Agreement** notices:

Rob Hadfield
Name

Chief Legal Officer
Title

Mailing Address:

One First Avenue, Parris Building #34

Navy Yard Plaza

Boston, MA 02129

Email Address: [***]

Phone: [***]

Fax: [***]

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments):

Eshane Dupree
Name

Accounts Payable
Title

One First Avenue, Parris Building #34

Navy Yard Plaza

Boston, MA 02129

Email Address: [***]

Phone: [***]

Fax: [***]

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

ATTACHMENT 1- ROYALTY PAYMENT INFORMATION

New Payment Options Effective March 2018

The License Number MUST appear on payments, reports and correspondence.

[***]

A-112-2021

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE ALAUNOS THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) IS CUSTOMARILY AND ACTUALLY TREATED AS PRIVATE.

PUBLIC HEALTH SERVICE

Amendment

This **Agreement** is based on the model Amendment Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the PHS within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by

National Cancer Institute

an Institute or Center (hereinafter referred to as the "**IC**") of the

NIH

and

Ziopharm Oncology, Inc., hereinafter referred to as the "**Licensee**",

having offices at One First Avenue, Parris Building #34, Navy Yard Plaza, Boston, MA 02129,

created and operating under the laws of Delaware.

Tax ID No.: 84-1475642

FOURTH AMENDMENT TO L-190-2019-0

This is the fourth amendment ("**Fourth Amendment**") of the agreement by and between the **IC** and Licensee having an effective date of May 28, 2019 and having IC Reference Number L-190-2019-0 ("**Agreement**"). This **Fourth Amendment**, having **IC** Reference Number L-190-2019-4 includes, in addition to the amendments made below, 1) a Signature Page, 2) Attachment 1 (Royalty Payment Information), and 3) Appendix A - Patent(s) or Patent Application(s).

WHEREAS, the **IC** and the **Licensee** desire that the **Agreement** be amended a fourth time as set forth below in order to bring additional patent rights within the scope of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, the **IC** and the **Licensee**, intending to be bound, hereby mutually agree to the following:

1) The cover page's "Serial Number(s) of Licensed Patent(s) or Patent Application(s)" section of the **Agreement**, including the complete list of Licensed Patent(s) or Patent Application(s) in this section, shall be deleted. Appendix A of this **Fourth Amendment** is hereby incorporated by reference herein.

2) Appendix A - Patent(s) or Patent Application(s) of the **Agreement** shall be deleted and replaced with Appendix A - Patent(s) or Patent Application(s) of this **Fourth Amendment**.

3) Within sixty (60) days of the execution of this **Fourth Amendment**, the **Licensee** shall pay the IC an amendment issue royalty in the sum of one hundred thirty thousand US Dollars ($130,000.00). Payment options may be found in Attachment 1.

4) In the event any provision(s) of the **Agreement** is/are inconsistent with Attachment 1, such provision(s) is/are hereby amended to the extent required to avoid such inconsistency and to give effect to the payment information in such Attachment 1.

5) All terms and conditions of the **Agreement** not herein amended remain binding and in effect.

6) The terms and conditions of this **Fourth Amendment** shall, at the **IC's** sole option, be considered by the IC to be withdrawn from the Licensee's consideration and the terms and conditions of this Fourth Amendment, and the Fourth Amendment itself, to be null and void, unless this **Fourth Amendment** is executed by the **Licensee** and a fully executed original is received by the **IC** within sixty (60) days from the date of the **IC's** signature found at the Signature Page.

7) This **Fourth Amendment** is effective upon execution by all parties.

SIGNATURES BEGIN ON NEXT PAGE

A-078-2021

FOURTH AMENDMENT TO L-190-2019/0

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Fourth Amendment** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the **IC**:

/s/ Richard U. Rodriguez — 4-30-21

Richard U. Rodriguez, MBA — Date
Associate Director
Technology Transfer Center
National Cancer Institute

National Institutes of Health Mailing Address or E-mail Address for **Agreement** notices and reports:

License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: [***]

For the **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

/s/ Robert Hadfield — 5-4-21

Signature of Authorized Official — Date

Name: Robert Hadfield
Title: General Counsel

A-078-2021

I. Official and Mailing Address for **Agreement** notices:

Rob Hadfield
Name

Chief Legal Officer
Title

Mailing Address:

One First Avenue, Parris Building #34

Navy Yard Plaza

Boston, MA 02129

Email Address: [***]

Phone: [***]

Fax: [***]

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments):

Eshane Dupree
Name

Accounts Payable
Title

One First Avenue, Parris Building #34

Navy Yard Plaza

Boston, MA 02129

Email Address: [***]

Phone: [***]

Fax: [***]

A-078-2021

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

ATTACHMENT 1- ROYALTY PAYMENT INFORMATION

New Payment Options Effective March 2018

The License Number MUST appear on payments, reports and correspondence.

[***]

A-078-2021

APPENDIX A - PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

Group A

[***]

Group B

[***]

Group C

[***]

Group D

[***]

Group E

[***]

Group F

[***]

A-078-2021

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE ALAUNOS THERAPEUTICS, INC. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) IS CUSTOMARILY AND ACTUALLY TREATED AS PRIVATE.

PUBLIC HEALTH SERVICE

Amendment

This **Agreement** is based on the model Amendment Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the PHS within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by

National Cancer Institute

an Institute or Center (hereinafter referred to as the "**IC**") of the

NIH

and

Ziopharm Oncology, Inc., hereinafter referred to as the "**Licensee**",

having offices at One First Avenue, Parris Building #34, Navy Yard Plaza, Boston, MA 02129,

created and operating under the laws of Delaware.

Tax ID No.: 84-1475642

A-239-2021

FIFTH AMENDMENT TO L-190-2019-0

This is the **fifth amendment** ("**Fifth Amendment**") of the agreement by and between the **IC** and Licensee having an effective date of May 28, 2019 and having **IC** Reference Number L-190-2019-0 ("**Agreement**"). This **Fifth Amendment**, having IC Reference Number L-190-2019-5 includes, in addition to the amendments made below, 1) a Signature Page, 2) Attachment 1 (Royalty Payment Information), and 3) Appendix A - Patent(s) or Patent Application(s).

WHEREAS, the **IC** and the **Licensee** desire that the **Agreement** be amended a fifth time as set forth below in order to bring additional patent rights within the scope of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, the **IC** and the **Licensee**, intending to be bound, hereby mutually agree to the following:

1) Appendix A - Patent(s) or Patent Application(s) of the **Agreement** shall be deleted and replaced with Appendix A - Patent(s) or Patent Application(s) of this **Fifth Amendment**. This Appendix A is further incorporated by reference on the cover page of the **Agreement**.

2) Within sixty (60) days of the execution of this **Fifth Amendment**, the **Licensee** shall pay the **IC** an amendment issue royalty in the sum of one US Dollar ($1.00). Payment options may be found in Attachment 1. The parties agree that the foregoing payment obligation shall be in lieu of the non-creditable, non-refundable amendment issue royalty set forth in Paragraph VII of Appendix C of the **Agreement** for all Additional T Cell Receptors added pursuant to this **Fifth Amendment**.

3) In the event any provision(s) of the **Agreement** is/are inconsistent with Attachment 1, such provision(s) is/are hereby amended to the extent required to avoid such inconsistency and to give effect to the payment information in such Attachment 1.

4) All terms and conditions of the **Agreement** not herein amended remain binding and in effect.

5) The terms and conditions of this **Fifth Amendment** shall, at the IC's sole option, be considered by the IC to be withdrawn from the Licensee's consideration and the terms and conditions of this **Fifth Amendment**, and the **Fifth Amendment** itself, to be null and void, unless this **Fifth Amendment** is executed by the **Licensee** and a fully executed original is received by the **IC** within sixty (60) days from the date of the **IC's** signature found at the Signature Page.

6) This **Fifth Amendment** is effective upon execution by all parties.

SIGNATURES BEGIN ON NEXT PAGE

A-239-2021

FIFTH AMENDMENT TO L-190-2019/0

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Fifth Amendment** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the **IC**:

/s/ Richard U. Rodriguez 8-11-21

Richard U. Rodriguez, MBA Date
Associate Director
Technology Transfer Center
National Cancer Institute

National Institutes of Health Mailing Address or E-mail Address for **Agreement** notices and reports:

License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: [***]

For the **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

/s/ Jill Buck 8-13-2021

Signature of Authorized Official Date

Name: Jill Buck
Title: EVP

A-239-2021

I. Official and Mailing Address for **Agreement** notices:

Michael A. Robinson
Name

Senior Vice President, Intellectual Property
Title

Mailing Address:

Ziopharm Ocology, Inc.

One First Avenue, Parris Building #34

Navy Yard Plaza

Boston, MA 02129

Email Address: [***]

Phone: [***]

Fax: [***]

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments):

Christine Legal
Name

Sr. Manager, Accounts Payable
Title

Ziopharm Oncology, Inc.

One First Avenue, Parris Building #34

Navy Yard Plaza

Boston, MA 02129

Email Address: [***]

Phone: [***]

Fax: [***]

A-239-2021

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

ATTACHMENT 1- ROYALTY PAYMENT INFORMATION

New Payment Options Effective March 2018

The License Number MUST appear on payments, reports and correspondence.

[***]

A-239-2021

APPENDIX A - PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

Group A

[***]

Group B

[***]

Group C

[***]

Group D

[***]

Group E

[***]

Group F

[***]

A-239-2021

Exhibit 10.44

Amendment #3

Cooperative Research and Development Agreement # 03111

"Development and Evaluation of Alaunos Therapeutics, Inc.'s Proprietary Non-viral Sleeping Beauty Vectors for Genetic Modification of Peripheral Blood Lymphocytes with Genes Encoding Mutated Tumor Neoantigen-specific T Cell Receptors (also referred to as Mutation Reactive T Cell Receptors) that Have Been Identified Using NCI Proprietary Methods"

IC Principal Investigator: Steven A. Rosenberg, M.D., Ph.D.

Collaborator: Alaunos Therapeutics, Inc. ("Alaunos")

The purpose of this amendment is to change certain terms of the above-referenced Cooperative Research and Development Agreement (CRADA). These changes are reflected below, and except for these changes, all other provisions of the original CRADA and Amendments #1 and 2 remain in full force and effect. Upon execution, IC and Alaunos will each retain a copy of this amendment.

The Parties agree:

1. Upon final signature, the term of the CRADA is extended retroactively for one (1) year, from January 9th, 2022 to January 9th, 2023.

2. Ziopharm Oncology, Inc. is changed to Alaunos Therapeutics, Inc. Collaborator's CRADA principal investigator is changed from Dr. Laurence Cooper to Dr. Drew Deniger effective with this Amendment. The address of Alaunos is changed to 8030 El Rio, Houston TX 77054. The Contacts Page is deleted in its entirety and replaced with the Contacts Page set forth in Exhibit 1. These changes are made throughout the CRADA including in the title.

SIGNATURES ON THE FOLLOWING PAGE

ACCEPTED AND AGREED TO:

For the National Cancer Institute

/s/ James H. Doroshow, M.D.	03/15/2022
James H. Doroshow, M.D. Deputy Director for Clinical and Translational Research, NCI	Date

For Alaunos:

/s/ Kevin S. Boyle, Sr.	03/15/2022
Name: Kevin S. Boyle, Sr. Title CEO	Date

Exhibit 1:

CONTACTS INFORMATION PAGE

CRADA Notices

For NCI:

Technology Transfer Specialist
National Cancer Institute
9609 Medical Center Drive
Bethesda, MD 20892-9702 MSC 9702
Rockville, MD 20850-9702 (express mail)
Tel: [***]
Fax: [***]

For Collaborators:

Chief Legal Officer
ALAUNOS THERAPEUTICS, INC.
8030 El Rio
Houston TX 77054
email: [***]

Patenting and Licensing

For IC:

Technology Transfer Center
National Cancer Institute
9609 Medical Center Drive
Bethesda, MD 20892-9702 MSC 9702
Rockville, MD 20850-9702 (express mail)
Tel: [***]
Fax: [***]

For Collaborator (same as above)

Finances

For IC:

Technology Transfer Manager for Finances
NCI, Technology Transfer Center
9609 Medical Center Dr., 1E-452, MSC 9702
Bethesda, MD 20892-9702
Tel: [***]
Email: [***]
EIN: 52-085811

For Collaborator:

Christine Legal
Sr. Manager, Accounts Payable
8030 El Rio St.
Houston TX 77054
[***]

Delivery of Materials Identified in Appendix B (if any)

For IC:

Steven A. Rosenberg, M.D., Ph.D.
Surgery Branch, NCI
10 Center Drive, MSC 1201
Bldg. 10, CRC Room 3-3940
Bethesda, MD 20892-1201
Tel. [***]
Fax: [***]

For Collaborator:

Drew Deniger, Ph.D.
Vice President, Research & Development
8030 El Rio
Houston TX 77054

Clinical Contact (as needed for Article 4.4.2)

For IC:

Steven A. Rosenberg, M.D., Ph.D.
Surgery Branch, NCI
10 Center Drive, MSC 1201
Bldg. 10, CRC Room 3-3940
Bethesda, MD 20892-1201
Tel. [***]
Fax: [***]

and

[***]

For Collaborator:

Drew Deniger, Ph.D.
Vice President, Research & Development
Alaunos Therapeutics, Inc.
8020 El Rio
Houston TX 77030
Email: [***]

Exhibit 10.52

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

This **FIRST AMENDMENT** to Loan and Security Agreement (this "Amendment") is entered into as of December 28, 2021, by and among (a) **SILICON VALLEY BANK**, a California corporation ("**SVB**"), in its capacity as administrative agent and collateral agent ("**Agent**"), (b) SVB, as a lender, (c) **SVB INNOVATION CREDIT FUND VIII, L.P.**, a Delaware limited partnership ("**SVB Capital**"), as a lender (SVB and SVB Capital and each of the other "Lenders" from time to time a party hereto are referred to herein collectively as the "**Lenders**" and each individually as a "**Lender**"), and (d) **ZIOPHARM ONCOLOGY, INC.**, a Delaware corporation ("**Borrower**").

RECITALS

A. Agent, Lenders, and Borrower have entered into that certain Loan and Security Agreement dated as of August 6, 2021 (as the same may from time to time be further amended, modified, supplemented or restated, the "**Loan Agreement**").

B. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Agent and Lenders amend the Loan Agreement to (i) revise certain milestones, and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

D. Agent and Lenders have agreed to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 1.1 (Term Loan Advance). Section 1.1 of the Loan Agreement hereby is amended and restated in its entirety and replaced with the following:

"**1.1 Term Loan Advance.**

(a) Availability. Borrower hereby acknowledges that prior to the First Amendment Effective Date, the Lenders, severally and not jointly, have made one (1) term loan advance to Borrower in an original principal amount equal to Twenty-Five Million Dollars ($25,000,000) according to each Lender's Term Loan Advance Commitment as set forth on Schedule II hereto (the "**Term Loan Advance**"). After repayment, the Term Loan Advance (or any portion thereof) may not be reborrowed.

(b) Repayment. Borrower shall repay the aggregate outstanding Term Loan Advance as set forth in Schedule I hereto. The periodic installments set forth herein include interest, and such installments are based upon the original principal amount of the Term Loan Advance, an assumed fixed rate of interest, and an assumed amortization term, notwithstanding the fact that the interest rate applicable to the Term Loan Advance may change from time to time. In the event that the applicable interest rate changes at any time as a result of any changes in the Prime Rate, Agent may, in its sole discretion, but shall not be required to, recalculate the installments of principal and interest, and Borrower shall pay such installments as they may be recalculated by Agent. Borrower acknowledges and agrees that any such recalculation shall not affect the Term Loan Maturity Date or any other terms or provisions in this Agreement or any other Loan Document, and that if Agent elects not to recalculate such installments, the Term Loan Advance may not fully amortize on the Term Loan Maturity Date. All outstanding principal and accrued and unpaid interest with respect to the Term Loan Advance, and all other outstanding Obligations under the Term Loan Advance, are due and payable in full on the Term Loan Maturity Date.

(c) Permitted Prepayment. Borrower shall have the option to make up to two (2) prepayments of the Term Loan Advance advanced by the Lenders under this Agreement, each in a minimum amount of at least Five Million Dollars ($5,000,000), provided Borrower (i) provides written notice to Agent of its election to prepay the Term Loan Advance at least five (5) Business Days prior to such prepayment, and (ii) pays to Agent, for the account of the Lenders in accordance with their respective Pro Rata Shares, on the date of such prepayment (A) all outstanding principal plus accrued and unpaid interest on the portion of the Term Loan Advance being prepaid, (B) the pro-rata portion of the Prepayment Premium due in connection with the Term Loan Advance being prepaid, (C) the pro-rata portion of the Final Payment due in connection with the Term Loan Advance being prepaid, and (D) all other sums, if any, that shall have become due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

(d) Mandatory Prepayment Upon an Acceleration. If the Term Loan Advance is accelerated by Agent, following the occurrence and during the continuance of an Event of Default, Borrower shall immediately pay to Agent, for the account of the Lenders in accordance with their respective Pro Rata Shares, an amount equal to the sum of (i) all outstanding principal plus accrued and unpaid interest with respect to the Term Loan Advances, (ii) the Prepayment Premium, (iii) the Final Payment and (iv) all other sums, if any, that shall have become due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts."

2.2 Section 1.4 (Payments; Pro Rata Treatment; Application of Payments; Debit of Accounts). Each reference to "Term Loan Advances" in Section 1.4(c) of the Loan Agreement hereby is replaced in each instance with "Term Loan Advance".

2.3 Section 1.9 (Procedures for Borrowing). Each reference to "Term Loan Advances" in Section 1.9 of the Loan Agreement hereby is replaced in each instance with "Term Loan Advance".

2.4 Section 5.15 (Cash Collateralization). Section 5.15 of the Loan Agreement hereby is amended and restated in its entirety and replaced with the following:

"**5.15 Cash Collateralization**.

(a) Cash Collateralization. If Borrower fails to achieve the Performance Milestones on or prior to August 31, 2022, Borrower hereby authorizes and directs Agent to immediately transfer to the Pledged Account (from any one or a combination of Borrower's accounts at SVB) an amount of cash and/or Cash Equivalents equal to fifty percent (50.0%) of the sum of (i) the then-outstanding principal balance of the Term Loan Advance, plus (ii) an amount equal to the Final Payment, in order to cash collateralize amounts owing from Borrower to Lenders in connection with the Term Loan Advance and the Final Payment (a "Cash Collateralization"), it being understood that the foregoing authorization shall constitute an immediate Cash Collateralization of the Obligations, irrespective of any delay by Agent in effecting such transfer.

(b) Partial Release of Cash Collateral Upon Certain Repayment Events.

(i) First Release. If a Cash Collateralization occurs, Agent and the Lenders hereby agree that so long as no Event of Default has occurred hereunder, if Borrower timely makes all scheduled payments of principal and interest owing in connection with the Term Loan Advance in accordance with the terms hereof, including the eighth (8th) scheduled payment of principal and interest on the Term Loan Advance due on April 1, 2023 (the "**8th Amortization Payment**"), so long as, after subtracting the 8th Amortization Payment, the sum of (y) the aggregate amount of outstanding principal plus accrued and unpaid interest remaining outstanding in connection with the Term Loan Advance, plus (z) the Final Payment, is equal to or less than Nine Million Seven Hundred Seventy Thousand Eight Hundred Thirty Three Dollars and Thirty Three Cents ($9,770,833.33), Agent shall, within ten (10) Business Days of the date of receipt of the 8th Amortization Payment, transfer from the Pledged Account to the Designated Deposit Account an amount equal to Two Million Five Hundred Thousand Dollars ($2,500,000) (the "**First Release**"). For the avoidance of doubt, the balance in the Pledged Account immediately after the First Release must equal Ten Million Dollars ($10,000,000) or more.

(ii) Second Release. If a Cash Collateralization occurs, Agent and the Lenders hereby agree that so long as no Event of Default has occurred hereunder, if Borrower timely makes all scheduled payments of principal and interest owing in connection with the Term Loan Advance in accordance with the terms hereof, including the tenth (10th) scheduled payment of principal and interest on the Term Loan Advance due on June 1, 2023 (the "**10th Amortization Payment**"), so long as, after subtracting the 10th Amortization Payment, the sum of (y) the aggregate amount of outstanding principal plus accrued and unpaid interest remaining outstanding in connection with the Term Loan Advance, plus (z) the Final Payment, is equal to or less than Five Million Six Hundred Four Thousand One Hundred Sixty Six Dollars and Sixty Six Cents ($5,604,166.66), Agent shall, within ten (10) Business Days of the date of receipt of the 10th Amortization Payment, transfer from the Pledged Account to the Designated Deposit Account an amount equal to Four Million Dollars ($4,000,000) (the "**Second Release**"). For the avoidance of doubt, the balance in the Pledged Account immediately after the Second Release must equal Six Million Dollars ($6,000,000) or more."

2.5 Section 9.10 (Defaulting Lender). Each reference to "Term Loan Advances" in Section 9.10 of the Loan Agreement hereby is replaced in each instance with "Term Loan Advance".

2.6 **Section 10 (Notices)**. Borrower's and SVB Capital's respective address for notices set forth in Section 10 of the Loan Agreement hereby is amended and restated in their entirety as follows:

"If to Borrower:	ZIOPHARM Oncology, Inc 8030 El Rio Street Houston, TX 77054 Attn: Melinda Lackey Email: MLackey@ziopharm.com
If to SVB Capital:	SVB Innovation Credit Fund VIII, L.P. c/o SVB Capital 2770 Sand Hill Road Menlo Park, CA 94025 Attn: SVB Capital Finance and Operations Email: svbcapitalcredit@svb.com; and SVBCapitalCreditFinance@svb.com"

2.7 **Section 13 (Definitions)**. The following terms and their respective definitions hereby are added or amended and restated in their entirety in Section 13.1 of the Loan Agreement, as appropriate, to read as follows:

"**Defaulting Lender**" is, subject to Section 9.10(b), any Lender that (a) has failed to (i) fund all or any portion of its Term Loan Advance within two (2) Business Days of the date such Term Loan Advance were required to be funded hereunder unless such Lender notifies Agent and Borrower in writing that such failure is the result of such Lender's reasonable determination that one or more conditions precedent to funding (each of which conditions precedent, together with any applicable default, shall be specifically identified in such writing) has not been satisfied, or (ii) pay to Agent or any other Lender any other amount required to be paid by it hereunder within two (2) Business Days of the date when due, (b) has notified Borrower or Agent in writing that it does not intend to comply with its funding obligations hereunder, or has made a public statement to that effect (unless such writing or public statement relates to such Lender's obligation to fund a Term Loan Advance hereunder and states that such position is based on such Lender's reasonable determination that a condition precedent to funding (which condition precedent, together with any applicable default, shall be specifically identified in such writing or public statement) cannot be satisfied), (c) has failed, within three (3) Business Days after written request by Agent or Borrower, to confirm in writing to Agent and Borrower that it will comply with its prospective funding obligations hereunder (provided that such Lender shall cease to be a Defaulting Lender pursuant to this clause (c) upon receipt of such written confirmation by Agent and Borrower), or (d) has, or has a direct or indirect parent company that has, (i) become the subject of an Insolvency Proceeding, or (ii) had appointed for it a receiver, custodian, conservator, trustee, administrator, assignee for the benefit of creditors or similar Person charged with reorganization or liquidation of its business or assets, including the Federal Deposit Insurance Corporation or any other state or federal regulatory authority acting in such a capacity; provided that a Lender shall not be a Defaulting Lender solely by virtue of the ownership or acquisition of any equity interest in that Lender or any direct or indirect parent company thereof by a Governmental Authority so long as such ownership interest does not result in or provide such Lender with immunity from the jurisdiction of courts within the United States or from the enforcement of judgments or writs of attachment on its assets or permit such Lender (or such Governmental Authority)

to reject, repudiate, disavow or disaffirm any contracts or agreements made with such Lender. Any determination by Agent that a Lender is a Defaulting Lender under any one or more of clauses (a) through (d) above shall be conclusive and binding absent manifest error, and such Lender shall be deemed to be a Defaulting Lender (subject to Section 9.10(b)) upon delivery of written notice of such determination to Borrower and each Lender.

"**First Amendment Effective Date**" is December 28, 2021.

"**Performance Milestones**" means Agent and the Lenders have received, evidence, satisfactory to Agent and the Lenders, confirming that Borrower has (a) achieved positive data in the first (1st) cohort of the Library TCR-T trial endorsed by an independent safety monitoring committee as a safe dose to proceed with; and (b) received at least Fifty Million Dollars ($50,000,000) in net cash proceeds after the First Amendment Effective Date from the sale of Borrower's equity securities on terms and conditions, acceptable to Agent and the Lenders.

"**Prepayment Premium**" shall be an additional fee, payable to Agent, for the ratable benefit of the Lenders based on their Pro Rata Share, with respect to the Term Loan Advance, in an amount equal to:

(a) for a prepayment of the Term Loan Advance made on or prior to the first (1st) anniversary of the Effective Date, three percent (3.0%) of the principal amount of the Term Loan Advance that is being prepaid;

(b) for a prepayment of the Term Loan Advance made after the first (1st) anniversary of the Effective Date, but on or prior to the second (2nd) anniversary of the Effective Date, two percent (2.0%) of the principal amount of the Term Loan Advance that is being prepaid; and

(c) for a prepayment of the Term Loan Advance made after the second (2nd) anniversary of the Effective Date, but prior to the Term Loan Maturity Date, one percent (1.0%) of the principal amount of the Term Loan Advance that is being prepaid.

"**Pro Rata Share**" is, as of any date of determination,, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of the Term Loan Advance held by such Lender by the aggregate outstanding principal amount of the Term Loan Advance.

"**Term Loan Advance**" is defined in Section 1.1 of this Agreement.

"**Warrant**" means, collectively, (a) that certain Amended and Restated Warrant to Purchase Stock dated as of the First Amendment Effective Date issued by Borrower to SVB, (b) that certain Amended and Restated Warrant to Purchase Stock dated as of the First Amendment Effective Date issued by Borrower to SVB Capital, (c) that certain Amended and Restated Warrant to Purchase Stock dated as of the First Amendment Effective Date issued by Borrower to Innovation Credit Fund VIII-A, L.P. and (d) any other warrant to purchase stock issued by Borrower in favor of SVB, SVB Capital or any of their Affiliates heretofore or hereafter, in each case as may be amended, modified, supplemented and/or restated from time to time.

2.8 **Section 13 (Definitions)**. The following defined terms and their respective definitions hereby are deleted from Section 13.1 and the balance of the Loan Agreement in their entirety:

"**Draw Period**", "**Equity Milestone**", "**Term A Loan Advance**", "**Term B Loan Advance**", "**Term B Milestone**", "**Term Loan Advances**"

2.9 Schedule I to the Loan Agreement hereby is replaced with Schedule I attached hereto.

2.10 Schedule II to the Loan Agreement hereby is replaced with Schedule II attached hereto.

3. Limitation of Amendments.

3.1 The amendments set forth in **Section 2**, above, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Agent and/or Lenders may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Agent and Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Agent on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any material law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Ratification of Perfection Certificate. Borrower hereby ratifies, confirms and reaffirms, all and singular, the terms and disclosures contained in that certain Perfection Certificate dated on the Effective Date delivered to Agent by Borrower and acknowledges, confirms and agrees that the disclosures and information Borrower provided to Agent in such Perfection Certificate have not changed, as of the date hereof.

6. Integration. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

7. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

8. Effectiveness. This Amendment shall be deemed effective upon (a) the due execution and delivery to Agent of the following, each in form and substance satisfactory to Agent: (i) this Amendment by each party hereto, (ii) a Bank Services Cash Pledge Agreement executed in favor of Agent by Borrower, and (iii) (x) that certain Amended and Restated Warrant to Purchase Stock dated as of the First Amendment Effective Date issued by Borrower to SVB, (y) that certain Amended and Restated Warrant to Purchase Stock dated as of the First Amendment Effective Date issued by Borrower to SVB Capital, and (z) that certain Amended and Restated Warrant to Purchase Stock dated as of the First Amendment Effective Date issued by Borrower to Innovation Credit Fund VIII-A, L.P., and (b) Borrower's payment to Agent of all Lenders' Expenses due and owing as of the date hereof, which may be debited from any of Borrower's accounts at SVB.

[*Balance of Page Intentionally Left Blank*]

In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

BORROWER:

ZIOPHARM ONCOLOGY, INC.

By: /s/ Kevin Boyle Sr.

Name: Kevin Boyle Sr.

Title: Chief Executive Officer

AGENT:

SILICON VALLEY BANK, as Agent

By: /s/ Lauren Cole

Name: Lauren Cole

Title: Director

LENDERS:

SILICON VALLEY BANK, as Lender

By: /s/ Lauren Cole

Name: Lauren Cole

Title: Director

SVB INNOVATION CREDIT FUND VIII, L.P., as Lender
By: SVB Innovation Credit Partners VIII, LLC, a
Delaware limited liability company, its General
Partner

By: /s/ Ryan Grammer

Name: Ryan Grammer

Title: Senior Managing Director

SCHEDULE I
LSA PROVISIONS

LSA Section	LSA Provision
1.1(a) – Term Loan Advance – Availability	The Term Loan Advance must be in an original principal amount equal to Twenty-Five Million Dollars ($25,000,000). After repayment, the Term Loan Advance (or any portion thereof) may not be reborrowed. The original principal amount of the Term Loan Advance shall not, at any time, exceed the Term Loan Availability Amount.
1.1(b) – Term Loan Advance – Repayment	Commencing on the Term Loan Amortization Date and continuing on each Payment Date thereafter, Borrower shall repay the aggregate outstanding Term Loan Advance to Agent, for the account of the Lenders, in (i) twelve (12) consecutive, equal monthly installments of principal, plus (ii) monthly payments of accrued interest at the rate set forth in Section 1.2(b).
1.2(a) – Interest Payments – Term Loan Advance	Interest on the principal amount of the Term Loan Advance is payable in arrears monthly (i) on each Payment Date commencing on the first (1st) Payment Date of the month following the month in which the Funding Date of the Term Loan Advance occurs, (ii) on the date of any prepayment and (iii) on the Term Loan Maturity Date.
1.2(b) – Interest Rate – Term Loan Advance	The outstanding principal amount of the Term Loan Advance shall accrue interest at a floating rate per annum equal to the greater of (i) seven and three-quarters of one percent (7.75%) and (ii) the Prime Rate plus the Prime Rate Margin, which interest shall be payable in accordance with Section 1.2(a).
1.2(e) – Interest Computation	Interest shall be computed on the basis of the actual number of days elapsed and a 360-day year for any Credit Extension outstanding.
13.2 – "Borrower"	"**Borrower**" means **ZIOPHARM ONCOLOGY, INC.**, a Delaware corporation.
13.2 – "Effective Date"	"**Effective Date**" is August 6, 2021.
13.2 – "Payment Date"	"**Payment Date**" is the first (1st) calendar day of each month.

13.2 – "Prime Rate"	"**Prime Rate**" is the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal or any successor publication thereto as the "prime rate" then in effect; provided that if such rate of interest, as set forth from time to time in the money rates section of The Wall Street Journal, becomes unavailable for any reason as determined by Agent, the "Prime Rate" shall mean the rate of interest per annum announced by SVB as its prime rate in effect at its principal office in the State of California (such SVB announced Prime Rate not being intended to be the lowest rate of interest charged by SVB in connection with extensions of credit to debtors); provided that, in the event such rate of interest is less than zero percent (0.0%) per annum, such rate shall be deemed to be zero percent (0.0%) per annum for purposes of this Agreement.
13.2 – "Prime Rate Margin"	"**Prime Rate Margin**" is four and one half of one percent (4.50%).
13.2 – "Term Loan Amortization Date"	"**Term Loan Amortization Date**" is September 1, 2022; provided, however, if Borrower achieves the Performance Milestones on or prior to August 31, 2022, the Term Loan Amortization Date shall automatically, with no further action required by the parties hereto, be extended to September 1, 2023.
13.2 – "Term Loan Availability Amount"	"**Term Loan Availability Amount**" is an aggregate principal amount equal to Twenty-Five Million Dollars ($25,000,000).
13.2 – "Term Loan Maturity Date"	"**Term Loan Maturity Date**" is August 1, 2023; provided, however, if Borrower achieves the Performance Milestones on or prior to August 31, 2022, the Term Loan Maturity Date shall automatically, with no further actions required by the parties hereto be extended to August 1, 2024.

SCHEDULE II

LENDERS AND COMMITMENTS

TERM LOAN COMMITMENTS

Lender	Term Loan Advance Commitment	Term Loan Advance Commitment Percentage
Silicon Valley Bank	$17,500,000	70.0000%
SVB Innovation Credit Fund VIII, L.P.	$7,500,000	30.0000%
TOTAL	**$25,000,000**	**100.0000%**

Exhibit 10.53

March 28, 2022

BY EMAIL

Raffaele Baffa, M.D., Ph.D.
28 Cliff Road
Wellesley, MA 02481

Dear Raffaele:

This letter agreement ("*Agreement*") confirms the terms of your separation from Alaunos Therapeutics, Inc., f/k/a ZIOPHARM Oncology, Inc. ("*Alaunos*" or the "*Company*").[1] Unless you rescind your assent as set forth in Section 5(viii) below, this Agreement shall be effective, final and binding upon the expiration of the Revocation Period set forth in Section 5(viii) (the "*Effective Date*").

1. Separation Date. On March 31, 2022 (the "*Separation Date*") you shall voluntarily resign your employment with the Company without Good Reason (as that term is defined in your Employment Agreement dated September 30, 2020, as amended on November 23, 2020; the "*Employment Agreement*"). On or about the Separation Date, the Company shall provide your final pay in accordance with applicable law ("*Final Pay*"). This Agreement shall become effective upon the expiration of the Revocation Period, as defined below (the "*Effective Date*").

2. Consideration. If you execute and do not rescind this Agreement, then the Company will provide you with the following (the "*Consideration*"):

(i) severance pay in the amount of $155,000, less all applicable income and payroll taxes, deductions and withholdings (the "*Severance Pay*"), which is equivalent to four (4) months of your base salary and which shall be paid in a lump sum within thirty (30) days after the Effective Date;

1. Except for the obligations set forth in Section 2, which shall be the obligations solely of Alaunos Therapeutics, Inc., whenever the terms "Alaunos Therapeutics, Inc.," "Alaunos" or the "Company" are used in this Agreement (including, without limitation, Section 5), they shall be deemed to include Alaunos Therapeutics, Inc. and any and all of its divisions, affiliates and subsidiaries and all related entities, and its and their directors, officers, employees, managers, supervisors, agents, successors and assigns.

(ii) regardless of whether you execute this Agreement, you are eligible to continue receiving group medical, dental and/or vision insurance pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("*COBRA*"), and the COBRA "qualifying event" shall be deemed to occur on the Separation Date. Provided you timely complete the required COBRA election forms and remain eligible, the Company will pay one hundred percent (100%) of the COBRA premiums for four (4) months; and

(iii) waive your obligation to repay the Sign-On Bonus as set forth in Section 4(c) of the Employment Agreement.

3. Acknowledgments. You acknowledge and agree that (i) this Agreement and the Consideration do not constitute a severance plan and shall confer no benefit on anyone other than Alaunos and you; (ii) the Consideration provided for herein is not otherwise due or owing to you under any employment agreement (oral or written); and (iii) except for the Final Pay and any vested monies due to under any retirement programs in which you participate, you have been paid and provided all wages, vacation pay, holiday pay, earned paid sick time, bonuses, commissions, leaves of absence, family and medical leave, and any other form of compensation or benefit that may be due to you now or that would have become due in the future in connection with your employment with or separation of employment from Alaunos.

4. Return of Company Property; Confidentiality; Trade Secrets; Non-Disparagement. You hereby agree to:

(i) promptly return all property and documents (whether in hard copy or electronic form) of Alaunos in your custody or possession on or before the Separation Date;

(ii) not represent yourself as an employee or agent of Alaunos after the Separation Date;

(iii) on the Separation Date, execute the Invention, Non-Disclosure, Non-Solicitation and Non-Competition Agreement attached hereto as ***Exhibit A***, which you acknowledge is in consideration for the Severance Pay and which shall supersede the *Invention, Non-Disclosure, Non-Solicitation and Non-Competition Agreement* previously signed by you on November 10, 2020 (the "*Prior Non-Compete Agreement*").

(iv) keep confidential and not publicize or disclose the existence and terms of this Agreement, other than to (a) an immediate family member, legal counsel, accountant or financial advisor, provided that any such individual to whom disclosure is made aware of these confidentiality obligations; or (b) a state or

federal tax authority or government agency to which disclosure is mandated by applicable state or federal law; and

(v) not make any statements that are disparaging about or adverse to the business interests of Alaunos or that are intended to or do harm the reputation of Alaunos, including, but not limited to, any statements that disparage any products, services, finances, employees, officers, capabilities or any other aspect of the business of Alaunos.

Your breach of this Section 4 will constitute a material breach of this Agreement and, in addition to any other legal or equitable remedy available to Alaunos, will relieve Alaunos of the obligation to provide any Consideration not already paid or provided and/or entitle Alaunos to recover any Consideration already paid or provided.

5. Release of Claims.

(i) You hereby acknowledge and agree that by signing this Agreement and accepting the Consideration, you are waiving your right to assert any form of legal claim against Alaunos (as defined in footnote number 1) of any kind whatsoever from the beginning of time through and including the Effective Date, except for claims related to the Company's failure to perform its obligations under this Agreement. Your waiver and release is intended to bar any form of legal claim, charge, complaint or any other form of action (jointly referred to as "*Claims*") against Alaunos seeking any form of relief including, without limitation, equitable relief (whether declaratory, injunctive or otherwise), the recovery of any damages or any other form of monetary recovery whatsoever (including, without limitation, back pay, front pay, compensatory damages, emotional distress damages, punitive damages, attorneys' fees and any other costs) against Alaunos up to and including the Effective Date. You understand that there could be unknown or unanticipated Claims resulting from your employment with Alaunos and the termination thereof and agree that such Claims are intended to be, and are, included in this waiver and release.

(ii) Without limiting the foregoing general waiver and release, you specifically waive and release the Company from any Claims arising from or related to your employment relationship with the Company or the termination thereof, including without limitation:

(a) Claims under any local, state or federal discrimination, harassment, fair employment practices or other employment related statute, regulation or executive order, including, without limitation, the Massachusetts Fair Employment Practices Act (also known as Chapter 151B), the Age

Discrimination in Employment Act, the Older Workers Benefits Protection Act ("*OWBPA*"), the Americans with Disabilities Act, the Genetic Information Nondiscrimination Act, the Pregnancy Discrimination Act, the Worker Adjustment and Retraining Notification Act, the National Labor Relations Act, the Civil Rights Act of 1991, and Title VII of the Civil Rights Act of 1964, each as they may have been amended through the Effective Date;

(b) Claims under any local, state or federal employment related statute, regulation or executive order relating to wages, hours, whistleblowing, leaves of absence or any other terms and conditions of employment, including, without limitation, the Fair Labor Standards Act, the Equal Pay Act of 1963, the Family and Medical Leave Act, the Massachusetts Payment of Wages Law (Massachusetts General Laws Chapter 149, §§ 148, 150), Massachusetts General Laws Chapter 149 in its entirety and Massachusetts General Laws Chapter 151 in its entirety (including, without limitation, the sections concerning payment of wages, minimum wage and overtime), each as they may have been amended through the Effective Date. You specifically acknowledge that you are waiving any Claims for unpaid wages under these and other statutes, regulations and executive orders;

(c) Claims under any local, state or federal common law theory; and

(d) any other Claim arising under other local, state or federal law.

(iii) The general release in this Section 5 is (a) not affected or limited by the recitation of the specific releases in this Section 5 and (b) shall not limit any right you may have to receive a whistleblower award or bounty for information provided to the Securities and Exchange Commission.

(iv) Consistent with federal and state discrimination laws, nothing in this release shall prohibit you from challenging the validity of this release under federal or state discrimination laws or from filing a charge or complaint of age or other employment related discrimination with the Equal Employment Opportunity Commission ("*EEOC*") or similar state agency, or from participating in any investigation or proceeding conducted by the EEOC or similar state agency. Further, nothing in this release or Agreement shall be deemed to limit the Company's right to seek immediate dismissal of such charge or complaint on the basis that your signing of this Agreement constitutes a full release of any individual rights under federal or state discrimination laws, or the Company's right to seek restitution or other legal remedies to the extent permitted by law of

the economic benefits provided to you under this Agreement in the event that you successfully challenge the validity of this release and prevail in any claim under federal or state discrimination laws.

(v) You have twenty-one (21) days to consider and accept the provisions of this Agreement. You agree that any changes to this Agreement, whether material or immaterial, will not restart the running of this 21-day period.

(vi) You may rescind your assent to this Agreement if, within seven (7) business days after you sign it the "*Revocation Period*"), you email a written notice of rescission to me.

6. Miscellaneous.

(i) This Agreement supersedes any and all prior oral and/or written agreements, and sets forth the entire agreement between Alaunos and you with respect to your separation from Alaunos, including, without limitation, the Employee Agreement and the Prior Non-Compete Agreement.

(ii) No variations or modifications of this Agreement shall be deemed valid unless in writing and signed by Alaunos and you. The provisions of this Agreement are severable, and if for any reason any part shall be found to be unenforceable, the remaining provisions shall be enforced in full.

(iii) The validity, interpretation and performance of this Agreement, and all other matters relating to your employment and separation of employment from Alaunos, shall be governed by and construed in accordance with the internal laws of the Commonwealth of Massachusetts, without giving effect to conflict of law principles. Both parties agree that any action, demand, claim or counterclaim relating to (a) your employment and separation of your employment, and (b) the terms and provisions of this Agreement or to its breach, shall be commenced in the Commonwealth of Massachusetts in a court of competent jurisdiction. Both parties further agree that any such dispute shall be tried by a judge alone, and both parties hereby waive and forever renounce the right to a trial before a civil jury in any such dispute.

Alaunos wants to ensure that you fully understand the terms and effects of this Agreement. To that end, you have been encouraged and given an opportunity to consult with legal counsel. By executing this Agreement, you are acknowledging that (a) you have been afforded sufficient time to understand this Agreement and consult with legal counsel; (b) your agreements and obligations under this Agreement are made voluntarily, knowingly and without duress; and (c) neither Alaunos nor its agents or representatives have made any representations inconsistent with the provisions of this Agreement.

If the foregoing correctly sets forth our arrangement, please sign, date and return this Agreement to me.

Very truly yours,

ALAUNOS THERAPEUTICS, INC.

/s/ Kevin S. Boyle, Sr.
Kevin S. Boyle, Sr.
Chief Executive Officer

Accepted and Agreed To Under Seal:

/s/ Raffaele Baffa, M.D., Ph.D.
Raffaele Baffa, M.D., Ph.D.

Dated: March 28, 2022

EXHIBIT A

INVENTION, NON-DISCLOSURE, NON-SOLICITATION AND NON-COMPETITION AGREEMENT

In consideration of the severance pay being provided to me by **Alaunos Therapeutics, Inc.** (hereinafter referred to as the "Company") pursuant to my Separation Agreement dated March 28, 2022, the adequacy of which is acknowledged by me, I agree as follows:

1. Proprietary Information

(a) I agree that all information, whether or not in writing, of a private, secret or confidential nature concerning the Company's business, business relationships or financial affairs (collectively, "Proprietary Information") is and shall be the exclusive property of the Company. By way of illustration, but not limitation, Proprietary Information may include inventions, products, processes, methods, techniques, formulas, compositions, compounds, projects, developments, plans, manufacturing information, technical information, strategies, research data, clinical data, financial data, personnel data, computer programs, customer and supplier lists, and contacts at or knowledge of actual or prospective customers, suppliers, vendors, clinical sites, or collaborators of the Company. I will not disclose any Proprietary Information to any person or entity other than employees of the Company (who have a business reason to receive such information) or use the same for any purposes (other than in the performance of my duties as an employee of the Company) without written approval by an officer of the Company, either during or after my employment with the Company.

(b) I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that is required by the Company) of all Inventions made by me during the period of my employment by the Company, which records shall be available to, and remain the sole property of, the Company at all times. I agree that all files, letters, memoranda, reports, records, data, sketches, drawings, laboratory notebooks, program listings, or other written, photographic, or other tangible material containing Proprietary Information, whether created by me or others, which shall come into my custody or possession, shall be and are the exclusive property of the Company to be used by me only in the performance of my duties for the Company. All such materials or copies thereof and all tangible property of the Company in my custody or possession shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) termination of my employment (whether voluntary or involuntary). After such delivery, I shall not retain any such materials or copies thereof or any such tangible property.

(c) I agree that my obligation not to disclose or to use information and materials of the types set forth in paragraphs (a) and (b) above, and my obligation to return materials and tangible property, set forth in paragraph (b) above, also extends to such types of information, materials and tangible property of third parties including but not limited to actual or prospective customers, suppliers

vendors, clinical sites, or collaborators of the Company to the Company or other third parties who may have disclosed or entrusted the same to me or the Company.

(d) I am also expected, both during and after my employment with the Company, to maintain the confidentiality of the Company's trade secrets. The term "trade secrets," as used in this Agreement, shall be given its broadest possible interpretation under Massachusetts law and under the Defend Trade Secrets Act of 2016 and shall include, but not be limited to, anything tangible or intangible, and whether or how stored (including without limitation, electronically kept or stored), which constitutes, represents, evidences or records a secret scientific, technical, merchandising, production, financial or management information, design, process, procedure, formula, invention or improvement; and other confidential and proprietary information and documents.

(e) I acknowledge and understand that: (i) I shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law; (ii) I shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; (iii) if I file a lawsuit for retaliation for reporting a suspected violation of law I may disclose the trade secret to my attorney and use the trade secret information in the court proceeding, provided I file any document containing the trade secret under seal and do not disclose the trade secret, except pursuant to court order.

(f) I understand that, notwithstanding the forgoing, this Agreement does not limit my ability to communicate with the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("Government Agencies"), including to report possible violations of federal law or regulation or making other disclosures that are protected under the whistleblower provisions of federal law or regulation, or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice, to any Government Agency.

2. Developments

(a) I will make full and prompt disclosure to the Company of all inventions, improvements, discoveries, methods, developments, software, and works of authorship, whether
patentable or not, which are created, made, conceived, or reduced to practice by me or under my direction or jointly with others during my employment by the Company whether or not during normal working hours or on the premises of the Company (all of which are collectively referred to in this Agreement as "Developments").

(b) I agree to assign and do hereby assign to the Company (or any person or entity designated by the Company) all of my right, title and interest in and to all Developments and all related patents, patent applications, copyrights and copyright applications. However, this paragraph 2(b) shall

not apply to Developments which do not relate to the present or planned business or research and development of the Company and which are made and conceived by me not during normal working hours, not on the Company's premises and not using the Company's tools, devices, equipment or Proprietary Information. I understand that, to the extent this Agreement shall be construed in accordance with the law of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this paragraph 2(b) shall be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes. I also hereby waives all claims to moral rights in any Developments.

(c) I agree to cooperate fully with the Company, both during and after my employment with the Company, with respect to the procurement, maintenance and enforcement of copyrights, patents and other intellectual property rights (both in the United States and foreign countries) relating to Developments. I shall sign all papers, including, without limitation, copyright applications, patent applications, declarations, oaths, formal assignments, assignments of priority rights, and powers of attorney, which the Company may deem necessary or desirable in order to protect its rights and interest in any Development. I further agree that if the Company is unable, after reasonable effort, to secure my signature on any such papers, any executive officer of the Company shall be entitled to execute any such papers as my agent and my attorney-in-fact, and I hereby irrevocably designate and appoint each executive officer of the Company as my agent and attorney-in-fact to execute any such papers on my behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in any Development, under the conditions described in this sentence.

(d) If, in the course of my employment with the Company, I incorporate a Prior Development into any product or service offered or sold by the Company, the Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and/or sell such Prior Development. Notwithstanding the foregoing, I agree that I will not incorporate, or permit to be incorporated, Prior Developments in any Company products without the Company's prior written consent.

3. Non-competition

(a) For a period of four (4) months after the termination or cessation of such employment for any reason (voluntarily or involuntarily), I will not directly or indirectly, as an individual proprietor, partner, stockholder, officer, employee, director, joint venturer, investor, lender, consultant, or in any other capacity whatsoever (other than as the holder of not more than one percent of the combined voting power of the outstanding stock of a publicly held company), engage in the business of researching, developing, designing, producing, manufacturing marketing or selling (or assisting any other person in researching, developing, designing, producing, manufacturing, marketing or selling) cancer treatment therapies with immune cells expressing engineered TCRs.

(b) If I violate the provisions of Section 3, I shall continue to be bound by the restrictions set forth in Section 3 until a period of four (4) months has expired without any violation of such provisions.

4. Non-Solicitation

(a) For a period of one year after the termination or cessation of such employment for any reason (voluntarily or involuntarily), I will not directly or indirectly:

(i) solicit, divert, take away or do business with, or attempt to solicit, divert, take away or do business with, any of the clients, customers or accounts, or prospective clients, customers or accounts, of the Company which were contacted, solicited or served by me while employed by the Company;

(ii) in any way interfere with the relationship between any such clients, customers or accounts and the Company; or

(iii) solicit or encourage any clients, customers, or accounts to terminate or diminish their relationship with the Company.

(b) For a period of two years after the termination or cessation of such employment for any reason (voluntarily or involuntarily), I will not directly or indirectly recruit, solicit or hire any employee, of the Company (who was employed or engaged by the Company at any time during my employment with the Company), or induce or attempt to induce any such employee of the Company to terminate his/her employment or engagement with, or otherwise cease his/her relationship with, the Company.

(c) If I violate the provisions of Section 4(a), I shall continue to be bound by the restrictions set forth in Section 4(a) until a period of one year has expired without any violation of such provisions. If I violate the provisions of Section 4(b), I shall continue to be bound by the restrictions set forth in Section 4(b) until a period of two years has expired without any violation of such provisions.

5. Other Agreements

I hereby represent that, except as I have disclosed in writing to the Company, I am not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of my employment with the Company or to refrain from competing, directly or indirectly, with the business of such previous employer or any other party. I further represent that my performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement to keep in confidence proprietary information, knowledge or data acquired by me in confidence or in trust prior to my employment with the Company, and I will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others.

6. United States Government Obligations

I acknowledge that the Company from time to time may have agreements with the other persons or with the United States Government, or agencies thereof, which impose obligations or

restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. I agree to be bound by all such obligations and restrictions which are made known to me and to take all action necessary to discharge the obligations of the Company under such agreements.

7. No Employment Contract

I understand that this Agreement does not constitute a contract of employment and does not imply that my employment will continue for any period of time.

8. Notification of New Employers

During my employment with the Company and for two years after my employment ends for any reason (voluntarily or involuntarily), I hereby agree to provide a copy of this Agreement to any employer or prospective employer, and I hereby authorize the Company to provide copies of this Agreement to any person or entity that may or does employ or do business with, or consider employing or doing business with, me in the future.

9. Miscellaneous

(a) The term "Company" shall include Alaunos Therapeutics, Inc. and any of its parents, subsidiaries, subdivisions, predecessors or affiliates. The Company shall have the right to assign, without my express consent, this Agreement to its successors and assigns, and all covenants and agreements hereunder shall inure to the benefit of and be enforceable by said successors or assigns.

(b) The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement.

(c) This Agreement supersedes all prior agreements, written or oral, between me and the Company relating to the subject matter of this Agreement.

(d) This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by me and the Company. I acknowledge that my covenants in this Agreement are given in exchange for, among other things, my employment and the terms and conditions of such employment. My covenants are not tied to my present role, title or responsibilities. I therefore agree that any change or changes in my duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

(e) No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(f) The restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by me to be reasonable for such purpose. I agree that any breach of this Agreement is likely to cause the Company substantial and irrevocable damage and therefore, in the event of any such breach, I agree that the Company, in addition to such other remedies which may be available, shall be entitled to seek specific performance, injunctive relief, or other equitable relief. I further understand and agree that in the event either party breaches or fails to honor any term of this Agreement, and the party seeking to enforce the terms of the this Agreement is successful in whole or in part in any legal or equitable action to defend its rights under or to enforce any terms of this Agreement, the successful party shall be entitled to payment of all costs, expenses and reasonable attorneys' fees associated with such action by the other.

(g) If any restriction set forth in Sections 3 or 4 is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

(h) This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to the conflicts of laws principles thereof. In addition, I agree that any dispute concerning this Agreement shall be heard exclusively by a court of competent jurisdiction within Massachusetts. By signing below, I acknowledge that I am subject to the exclusive personal jurisdiction of the Massachusetts courts in any county where the Company has operations or facilities. Both parties further agree that any such dispute shall be tried by a judge alone, and both parties hereby waive and forever renounce the right to a trial before a civil jury in any such dispute.

Signature Page Follows.

Invention, Non-Disclosure and Non-Competition Agreement

Alaunos Therapeutics, Inc.

/s/ Melinda Lackey
Melinda Lackey, Senior Vice President, Legal

March 28, 2022
Date

By signing and returning this signed Agreement to the Human Resources Department of Alaunos Therapeutics, Inc., I hereby acknowledge that I have received the Agreement, have fully reviewed it, and will abide by its terms at all times.

Intending to be legally bound hereby, I have signed this Agreement under seal as of the day and year written below. I hereby acknowledge that I have been advised and am aware of my right to consult with an attorney prior to signing this Agreement.

/s/ Raffaele Baffa, M.D., Ph.D.
Raffaele Baffa, M.D., Ph.D.

March 28, 2022
Date

Exhibit 21.1

Subsidiaries of the Registrant.

ZIOPHARM Oncology, Ltd (United Kingdom)
ZIOPHARM Oncology, Ltd (Ireland)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Nos. 333-129884, 333-134280, 333-142701, 333-160496, 333-167925, 333-185433, 333-199304, 333-220804, 333-228291, 333-238090 and 333-241698) 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 and 333-232283) on Form S-3 of Alaunos Therapeutics, Inc. of our report dated March 30, 2022, 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, 2021.

/s/ RSM US LLP

Boston, Massachusetts
March 30, 2022

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 30, 2022

/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, 2021, 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 30, 2022