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, 2024

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.)**
2617 Bissonnet Street, Suite 233 **Houston, TX** **(Address of Principal Executive Offices)**	**77005** **(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 Capital Market**

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates was $10,801,553 June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based on a total of 1,543,079 shares of common stock held by non-affiliates and a closing price of $7.00 as reported on the Nasdaq Capital Market on June 30, 2024. 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 31, 2025, there were 1,601,252 shares of the registrant's common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the Registrant's 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

Alaunos Therapeutics, Inc.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2024

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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: "aim", “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “project,” “target,” "potential," “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 successfully implement our strategic reprioritization or realize any or all of the anticipated benefits once implemented;
- our ability to raise substantial additional capital to continue as a going concern and fund our planned operations in the near term and our strategic reprioritization in the longer term;
- our ability to successfully consummate any strategic transactions, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions;
- estimates regarding our expenses, use of cash, cash runway, timing of future cash needs and anticipated capital requirements;
- our ability to license additional intellectual property to support our strategic reprioritization or out-license our intellectual property 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 collaborations and licenses;
- our expectation of developments and projections relating to competition from other pharmaceutical and biotechnology companies or our industry;
- our plans relating to conducting future *in vitro* testing, *in vivo* efficacy studies, and non-clinical and investigational new drug or IND-enabling activities;
- the anticipated amount, timing and accounting of contract liabilities, milestones and other payments under licensing, collaboration or acquisition agreements, research and development costs and other expenses;
- our ability to remain listed on the Nasdaq Capital Market; and
- our intellectual property position, including the strength and enforceability of our intellectual property rights.

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, level of activity, performance or achievements to be materially different from any future results, level of activity, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results, levels of activity or performance of achievements to differ materially from current expectations include, among other things, those described under Part I, Item 1A, “Risk Factors” and elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context requires otherwise, references in this Annual Report to “Alaunos,” the “Company,” “we,” “us” or “our” refer to Alaunos Therapeutics, Inc.

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®, hunTR®, and Ziopharm® 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, results of operations, cash flows and prospects 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:

- Our strategic reprioritization may not be successful, may not yield the desired results and we may be unsuccessful in identifying and implementing any strategic transaction.
- If a strategic transaction is not consummated, our Board of Directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- We may require substantial additional financial resources to continue as a going concern, including through the strategic review process, and if we raise additional funds it may affect the value of your investment in our common stock.
- Our ability to consummate a strategic transaction depends on our ability to retain our current employees and consultants.
- Our stock price has been, and may continue to be, volatile.
- Our decreasing cash reserves may result in our shareholder equity falling below $2,500,000 as required by Nasdaq Listing Rule 5550(b)(1), which may result in receipt of a delisting notice from Nasdaq. Delisting could prevent us from maintaining an active, liquid and orderly trading market for our common stock and may impact our ability to consummate certain strategic transactions.
- Since we effectuated a reverse stock split within the past year, should the trading price of our common stock fall again below the Minimum Bid Price requirement, we may be issued a delisting decision.
- We have identified a material weakness and failed to maintain an effective internal control environment, which may result in material misstatements of our financial statements or have a material adverse effect on our business or stock price.
- For our small molecule oral obesity program or should we resume development of our TCR-T product candidates, we may not be able to commercialize them, generate significant revenues, or attain profitability.
- Our small molecule obesity program is early stage and may encounter issues with manufacturing of the active pharmaceutical ingredient(s) or with the *in vitro* or *in vivo* studies that could preclude clinical trials or be costly to address with respect to time or money.
- For our small molecule oral obesity program or should we resume development of our TCR-T product candidates, any 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 significant 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.
- For our small molecule oral obesity program, or should we resume development of our TCR-T product candidates, if we fail to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, our business will suffer materially.
- The termination of our TCR-T related licenses and research and development agreements could limit our ability to resume our TCR-T clinical trial or begin new clinical trials.
- We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.
- 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.
- The gene transfer vectors from the *Sleeping Beauty* system used to manufacture our TCR-T 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.
- 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.
- If physicians and patients do not accept and use our product candidates, once approved, or if we do not obtain coverage and adequate reimbursement from payors, our ability to generate revenue from sales of our products will be materially and adversely impaired.
- Our small molecule and immuno-oncology product candidates may face competition in the future from generics or biosimilars and/or new technologies and our pending patent applications may not be granted, further limiting our ability to compete with other companies.

- If we 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 materially impaired.
- 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.
- We have and will rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cybersecurity 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 materially and adversely affect our business and reputation.
- 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.
- 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.
- 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.
- Our ability to use net operating loss carryforwards and research tax credits to reduce future tax payments may be limited or restricted.
- The exercise of outstanding warrants, and issuance of equity awards may have a dilutive effect on our stock, and negatively and materially impact the price of our common stock.
- 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 significantly harm the market price of 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.

PART I

Item 1. Business

Overview

We are a preclinical stage obesity and metabolic health drug development company that is aiming to develop a small molecule-based drug to treat obesity and other metabolic disorders that have a differentiated profile relative to currently marketed and in development oral and injectable products. We believe ALN1001 and related small molecule product candidates are distinct in that they do not rely on hormonal manipulation, which is common with many obesity treatments. We aim to develop an oral obesity compound that addresses many of the shortcomings of injectable GLP-1 receptor agonists including preserving lean muscle mass. We engaged a contract development and manufacturing organization or CMDO to manufacture active pharmaceutical ingredients for our small molecule product candidates and initiated *in vitro* testing of our candidates in the fourth quarter 2024.

The ongoing *in vitro* study aims to evaluate the impact of ALN1001 and its derivatives on lipid deposition and gene expression. This study evaluates if genes related to thermogenic activity, lipid metabolism, and energy regulation are activated or deactivated by treatment, to determine if these compounds positively affect fat and energy metabolism. The results of this study, which are expected early second quarter of 2025, will provide critical insights into the development strategy for ALN1001 and its derivatives for obesity, metabolic disorders, and inflammation. Drug development candidates most effective in increasing metabolic activity and reducing fat accumulation may be advanced to evaluation of the compounds in rodent models of obesity.

As is standard in the industry, if the aforementioned *in vitro* study is successful, we plan to conduct a proof-of-concept diet-induced obesity or DIO mouse study to validate our mechanism of action by the third quarter of 2025 before proceeding to Investigational New Drug or IND Application enabling studies. Our ability to execute on this plan is dependent on study results and our ability to raise additional capital or partner these assets with other companies or research institutions.

Obesity Market

Obesity remains one of the most pressing public health challenges globally, with rates continuing to rise across many regions, particularly in the United States, Europe, and parts of Asia. It is closely linked to a range of comorbid conditions, including type 2 diabetes, cardiovascular diseases, and certain cancers, which exacerbates the overall healthcare burden. The obesity market is seeing increased attention, driven by growing awareness, better treatment options, and emerging scientific breakthroughs.

The global obesity market is experiencing rapid growth. Globally, the market size for branded obesity drugs was $6 billion in 2023 and is estimated that it will reach $105.0 billion by 2030. This growth is fueled by the rising obesity prevalence, evolving patient demographics, and increasing demand for effective weight-management solutions. The shift toward more personalized treatments and the need for long-term weight management are key drivers of this growth.

The current treatment landscape for obesity consists of a combination of lifestyle interventions, pharmaceuticals, and surgical options. Lifestyle interventions—dietary changes and physical activity—are the first-line treatment for most individuals, but many struggle to achieve and maintain significant weight loss through these methods alone.

Traditional weight-loss medications (e.g., OrlistatTM) are still used, though their side effects and modest results have limited their appeal. Newer drugs, like GLP-1 receptor agonists (e.g., OzempicTM, WegovyTM), are quickly becoming the gold standard in the market. These drugs, which mimic the action of gut hormones to promote satiety and reduce appetite, have shown remarkable efficacy in clinical trials and are significantly improving patient outcomes.

The success of GLP-1s has led to a surge in interest from both pharmaceutical companies and patients. However, issues such as high cost, insurance reimbursement, and potential long-term side effects remain areas of concern.

The future of the obesity market is promising, with new therapies, enhanced patient targeting, and continued scientific breakthroughs on the horizon. As the global obesity epidemic continues to grow, demand for more effective and affordable treatments will likely continue to rise. However, success will depend on overcoming challenges related to cost, access, and patient adherence. Advancements in personalized medicine, non-invasive treatments, and innovative drug mechanisms will shape the next phase of the obesity treatment landscape.

The obesity market today is vibrant and expanding, but still in need of accessible, scalable, and sustainable solutions to effectively manage this complex and widespread health issue.

Cell Therapy

We were historically involved in developing adoptive T-cell receptor, or 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 leveraged our cancer hotspot mutation TCR library and our proprietary, non-viral Sleeping Beauty gene transfer platform to design and manufacture patient-specific cell therapies that target neoantigens arising from common tumor-related mutations in key oncogenic genes, including KRAS, TP53 and EGFR. In collaboration with The University of Texas MD Anderson Cancer Center, or MD Anderson, we were enrolling and treating patients for a Phase 1/2 clinical trial evaluating 12 TCRs reactive to mutated KRAS, TP53 and EGFR from our TCR library for the investigational treatment of non-small cell lung, colorectal, endometrial, pancreatic, ovarian and bile duct cancers, which we refer to as our TCR-T Library Phase 1/2 Trial. More information regarding our TCR-T clinical trial, strategy and approved is detailed on our 2023 Form 10-K.

Despite the encouraging TCR-T Library Phase 1/2 Trial data, based on the substantial cost to continue development and the current financing environment, we announced in August 2023 that we would not pursue any further development of our TCR-T clinical programs. On August 14, 2023, the Company announced a strategic reprioritization of its business and wind down of its TCR-T Library Phase 1/2 Trial. We are currently working to close the TCR-T clinical trial internally and externally with the Federal Drug Administration or FDA.

The Company continues to explore strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions.

Preclinical and Clinical Development

Preclinical Development of our Obesity Product Candidates

We aim to develop an oral obesity compound that addresses many of the shortcomings of injectable GLP-1 receptor agonists including preserving lean muscle mass. The ongoing *in vitro* study aims to evaluate the impact of ALN1001 and its derivatives on lipid deposition and gene expression. This study evaluates if genes related to thermogenic activity, lipid metabolism, and energy regulation are activated or deactivated by treatment, to determine if these compounds positively affect fat and energy metabolism. The results of this study, which are expected early second quarter of 2025, will provide critical insights into the development strategy for ALN1001 and its derivatives for obesity, metabolic disorders, and inflammation. Drug development candidates most effective in increasing metabolic activity and reducing fat accumulation may be advanced to evaluation of the compounds in rodent models of obesity.

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Manufacturing of our Obesity Product Candidates

We currently outsource the manufacturing of our active pharmaceutical ingredient or API to a third party vendor with extensive experience in manufacturing small molecule drug products.

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.

Alaunos Patents & Patent Applications

As of December 31, 2024, we have six 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 offered 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 depended 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 Item Ia. Risk Factors—*"*Risks 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

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

On January 13, 2015, we and Precigen (later assigned to PGEN) entered into the MD Anderson License, granting us an exclusive global license to technologies from MD Anderson, primarily related to CAR T-cell therapies, non-viral gene transfer, genetic modification of immune cells, NK cells, and TCRs, developed by Laurence Cooper, M.D., Ph.D., our CEO from May 2015 to February 2021.

On August 17, 2015, we, Precigen, and MD Anderson executed the 2015 R&D Agreement, establishing the scope and terms for transferring existing and future research programs and technologies. Precigen's rights were later assigned to us effective October 5, 2018. A joint steering committee, including two members from our company and one from MD Anderson, oversees activities under this agreement.

Under the MD Anderson License, we funded R&D activities for three years at $15-20 million annually. Amendments to the 2015 R&D Agreement extended its term first to April 15, 2021, then to December 31, 2026, and allowed existing funds to support costs under the 2019 R&D Agreement, initiated on October 22, 2019, focusing on the TCR program.

The MD Anderson License term ends upon the later of the expiration of all licensed patents or the twentieth anniversary of the agreement. Post-expiration, we retain a perpetual, royalty-free, sublicensable license. MD Anderson may convert the license to non-exclusive after ten years if we fail commercial diligence, or terminate specific technologies after five years if diligence requirements tied to funding or third-party contracts aren't met, subject to specified cure periods. MD Anderson can terminate upon uncured material breach or certain insolvency events and through mutual agreement

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

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

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

Under the 2019 R&D Agreement, we agreed, beginning on January 1, 2021, to reimburse MD Anderson up to a total of $20.0 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, if any. We are required to make performance-based payments upon the successful completion of clinical and regulatory benchmarks relating to our TCR products. The aggregate potential benchmark payments are $36.5 million, of which only $3.0 million will be due prior to the first marketing approval of our TCR products. The royalty rates and benchmark payments owed to MD Anderson may be reduced upon the occurrence of certain events. We also agreed to sell our TCR products to MD Anderson at preferential prices and will sell our TCR products in Texas exclusively to MD Anderson for a limited period of time following the first commercial sale of our TCR products.

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

In connection with the execution of the 2019 R&D Agreement, on October 22, 2019, we issued MD Anderson a warrant to purchase 22,222 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 $0.15 per share, expires on December 31, 2026, and vests upon the occurrence of certain clinical milestones. As of December 31, 2024, the milestones have not been met.

Governmental Regulation and Product Approval

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 pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 an NDA or biologics license application or 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 NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA; and
- FDA acceptance, review and approval, or licensure, of the NDA or 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 relied 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.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in significant part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. Third-party payors are increasingly challenging the price, examining the medical necessity of and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

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

The downward pressure on health care costs in general, particularly prescription drugs and biologics, has become very intense. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. As a result, increasingly high barriers are being erected to the entry of new products. The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide favorable coverage and adequate reimbursement. In addition, emphasis on managed care in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Health Care Laws Governing Interactions with Healthcare Providers

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

- The federal Anti-Kickback Statute, which regulates our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- Federal civil and criminal false claims laws, including the False Claims Act which permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal civil and criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities and individuals subject to the law including certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as individuals and entities that perform services for them which involve the use, or disclosure of, individually identifiable health information, known as business associates as well as their covered subcontractors;
- Requirements to report annually to the Centers for Medicare & Medicaid Services, or CMS, certain financial arrangements with physicians and teaching hospitals, as defined in the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, and its implementing regulations, including reporting any "transfer of value" made or distributed to prescribers and teaching hospitals, and reporting any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year; and
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities; state laws that require the reporting of information related to drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Healthcare Reform Efforts

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

In March 2010, President Obama signed into law the ACA, which included measures that have significantly changed the way healthcare is financed by both governmental and private insurers. The ACA, among other things, imposed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or

reformulated drugs, established annual fees on manufacturers and importers of certain branded prescription drugs and biologic agents, promoted a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program and imposed a number of substantial new compliance provisions related to pharmaceutical companies' interactions with healthcare practitioners. The ACA also expanded eligibility for Medicaid programs and introduced a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research and a new Center for Medicare & Medicaid Innovation at CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, legal and political challenges to certain aspects of the ACA. For example, President Trump signed several executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed legislation that would repeal the ACA in total, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Further, President Biden had issued an executive order that instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA, though this and similar Biden-era policies are currently being revisited by the current Trump administration. There had been a number of health reform initiatives by the Biden administration that have impacted the ACA, including adoption of the Inflation Reduction Act, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminated the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and implementing a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future, particularly in light of the Trump administration's interest in reducing federal expenditures to include those under federal healthcare programs.. It is unclear how any such challenges and the cost reduction measures of the Trump administration will impact ACA and our business. The ultimate content, timing or effect of any healthcare reform measures on the U.S. healthcare industry is unclear.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which went into effect on April 1, 2013. This 2% reduction was temporarily suspended during the COVID-19 pandemic, but has since been reinstated and, unless Congress and/or the Executive Branch take additional action will extend to 2032. 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. On November 30, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers; the implementation of these provisions has also been delayed by the IRA until January 1, 2032. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, which was set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. The IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively starting

in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry.

At the state level, legislatures have increasingly enacted legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

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

The Foreign Corrupt Practices Act, or the FCPA, prohibits any United States individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the government of the United States, 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 aim to develop an oral obesity compound that addresses many of the shortcomings of injectable GLP-1 receptor agonists including preserving lean muscle mass. The goal of this program is to develop a drug with a differentiated profile relative to currently marketed and in development oral and injectable products. We believe our small molecule product candidates are distinct in that they do not rely on hormonal manipulation, which is common with many other obesity treatments. These treatments are currently being developed or marketed by many pharmaceutical or biotech companies at various stages. While our small molecule product candidates are different from these competitors' product offerings, our goals are the same, to treat obesity, and therefore, we are competitors in the same market. These competitors include 35 Pharma, Aardvark Tx, Altimmune, Amgen, Amplifier, Aphaia Pharma, Ascletis, AstraZeneca, Astrizi, BioAge Labs, Biomea Fusion, Biomed Industries, Boehringer Ingelheim, Clearmind, Corbus Pharma, Corxel, Currax Pharma, Eli Lilly, Empros Pharma, EndevicaBio, Entera/Opko, Epitomee, ERX Pharma, Gan & Lee Pharmaceuticals, Gilead, Glaceum, Glyscend, Halia Therapeutics, Hansoh Pharmaceutical, Huadong Medicine, Kailera/Hengrui, Kallyope, Lexicon, Merck, Metsera, Mindrank AI, Neurogastrx, NodThera, Novo Nordisk, OrsoBio, Pelagos, Pep2Tango Therapeutics, Pfizer, ProGen/Rani Therapeutics, Regeneron, Regor, Response Pharmaceuticals, Roche, Scilex, Scohia Pharma, Shionogi, Structure Tx, Syntis Bio, Terns Pharma, Verdiva Bio/Sciwind, Verge Genomics, Veru, and Viking Therapeutics.

We also believe our novel hunTR discovery engine demonstrated the 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,* was less complex relative to many of our competitors' viral approaches. Finally, our TCR-T Phase 1/2 Library Trial was designed to allow us to treat patients quickly and efficiently in many different indications with a tumor mutation and HLA matching one or more of the several TCRs in our library, which we believe gives us a distinct competitive advantage. However, the development and commercialization for new products to treat cancer, including the indications we pursued, 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. These competitors include 2Seventy Bio, Achilles Therapeutics, Adaptimmune Therapeutics, Affini-T Therapeutics, Annoca, ArsenalBio, BioNTech, Bristol-Myers Squibb, Immatics, Iovance Biotherapeutics, Kite (a Gilead company), Lion TCR, Lyell Immunopharma, Medigene, Nurix Therapeutics, Neogene Therapeutics (a member of the AstraZeneca group), NexImmune, PACT Pharma, Precigen, Tactiva Therapeutics, Takara Bio, TCR^2 Therapeutics, T-Cure BioScience, T-knife Therapeutics, Triumvira Immunologics, TScan Therapeutics, Turnstone Biologics, Zelluna Immunotherapy and others.

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 1, 2025, we had 1 full-time employee who is engaged in administration and no part-time employees. Our employee is not subject to a collective bargaining agreement. In addition, we have engaged various consultants with our material consulting agreement being described below.

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

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.

We continue to have in place several material consulting agreements to ensure business continuity.

The Boyle Consulting Agreement

On January 1, 2024, we also entered into a consulting agreement (the "Boyle Consulting Agreement") with Mr. Kevin S. Boyle, Sr. our former Chief Executive Officer and Director, pursuant to which he provided strategic and advisory services to us. The Boyle Consulting Agreement had a six months term. The Boyle Consulting Agreement provided for compensation at a fixed rate of $15,000 per month and reimbursement for any usual and customary expenses incurred by Mr. Boyle in connection with performing services pursuant to the Boyle Consulting Agreement.

The Lackey Consulting Agreement

Ms. Lackey, our former Senior Vice President, Legal & Administration, continues to be engaged by us under her consulting agreement , effective November 16, 2023, (the "Lackey Consulting Agreement") pursuant to which Ms. Lackey continues to provide legal and administrative services to us. The Lackey Consulting Agreement will continue indefinitely until terminated by the Company or Ms. Lackey upon 30 days prior written notice. The Lackey Consulting Agreement provides for compensation at a fixed rate of $400 per hour and reimbursement by the Company for any usual and customary expenses incurred by Ms. Lackey in connection with performing services pursuant to the Lackey Consulting Agreement.

Mr. Groenewald's Engagement

On February 22, 2024, the Company and Ferdinand Groenewald entered into a consulting agreement (the "Groenewald Consulting Agreement"), effective February 22, 2024, pursuant to which Mr. Groenewald will lead accounting and financial reporting activities of the Company. Mr. Groenewald will serve as the Company's Vice President, Finance taking over from Mr. Wong our former Vice President of Finance. The Groenewald Consulting Agreement will continue indefinitely until terminated by either party upon 30 days' advance notice. The Groenewald Consulting Agreement provides for compensation at a fixed rate of $15,000 per month and reimbursement by the Company for any usual and customary business expenses incurred by Mr. Groenewald in connection with performing services pursuant to the Groenewald Consulting Agreement. In addition, the Groenewald Consulting Agreement provides for the Company to indemnify Mr. Groenewald on terms customary for officers.

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 2617 Bissonnet Street, Suite 233, Houston, Texas 77005, and our telephone number is (346) 355-4099.

Available Information

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

Item 1A. Risk Factors

An investment in our common stock is risky. In addition to the other information in this Annual Report on Form 10-K, you should carefully consider the following risk factors in evaluating us and our business. If any of the events described in the following risk factors were to occur, our business, financial condition, results of operations, cash flows and 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 Annual Report on Form 10-K 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, results of operations, cash flows and prospects. Additional risks that we currently do not know about, or that we currently believe to be immaterial, may also impair our business, financial condition, results of operations, cash flows and prospects. Certain statements below are forward-looking statements. See "Special Note Regarding Forward-Looking Statements" in this Annual Report.

RISKS RELATED TO OUR STRATEGIC REPRIORITIZATION

****Our strategic reprioritization may not be successful, may not yield the desired results and we may be unsuccessful in identifying and implementing any strategic transaction.***

On August 14, 2023, we announced a strategic reprioritization of our business and wind down of our TCR-T Library Phase 1/2 Trial. In connection with the reprioritization, we have reduced our workforce by approximately 95% to date and we continue working to reduce costs in order to extend our cash runway. We continue to explore strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions. We engaged Cantor Fitzgerald & Co., or Cantor, to act as strategic advisor for this process. In addition, while we are evaluating several potential in-licensing opportunities in obesity, oncology and virology, there is no assurance that any of these potential opportunities will come to fruition.

We believe there is value in our hunTR® TCR discovery platform. However, the platform is experimental. There can be no assurances that we can succeed in improving the platform's appeal and increasing its value. We may be unable to successfully monetize the platform or any TCRs we discovered, either through partnerships or out-licensing.

We expect to devote substantial time and resources to exploring strategic alternatives that our Board of Directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our Board of Directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business.

In addition, potential counterparties in a strategic transaction involving the Company may place minimal or no value on our assets or our public listing. Further, should we resume the development of our product candidates, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving the Company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affect our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

We also believe that the potential value of our obesity program for patients and our stockholders is high but that expectation may not be recognized by potential strategic alternative partners or by the market. We may be forced to execute a transaction that undervalues or eliminates the obesity program entirely despite our best efforts to continue work on the assets if that transaction is in the best interest of the stockholders.

If we are not successful in setting forth a new strategic path for the Company, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of the Company could cause our stock price to fluctuate significantly.

Even if we successfully consummate a transaction from our strategic assessment, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.

Our ability to realize the anticipated benefits of any potential business combination or any other result from our strategic assessment is highly uncertain. Any anticipated benefits will depend on a number of factors, including our ability to integrate with any future business partner, the success of any future business we may engage in following the transaction and our ability to obtain value for our product candidates or technologies, if divested. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated timeframe, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition. Furthermore, our stockholders may experience substantial dilution as a result of the transaction without receiving the expected commensurate benefit, or only receiving part of the commensurate benefit to the extent we are able to realize only part of the expected strategic and financial benefits currently anticipated from a transaction.

****We may require substantial additional financial resources to continue as a going concern, including through the strategic review process, and if we raise additional funds, this may materially and negatively affect the value of your investment in our common stock.***

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the year ended December 31, 2024, we had a net loss of $4.6 million, and, as of December 31, 2024, our accumulated deficit since inception in 2003 was $920.4 million. Although we are in the process of implementing a restructuring plan, or the Plan, whereby we are winding down our TCR-T Library Phase 1/2 Trial, other development programs and implemented a reduction in force, in order to reduce operating expenditures and net losses, as discussed above, there can be no assurances we will be successful at all, or in the amount we anticipate. During that process, we also internally developed an obesity program whereby we are now performing pre-clinical studies on our obesity assets.

As of December 31, 2024, we have approximately $1.1 million of cash and cash equivalents. Following implementation of the Plan, we anticipate our cash resources will be sufficient to fund our operations into the second quarter of 2025. We have not set a timetable for completion of the strategic review process and the timing of consummating a strategic transaction, if any, is not entirely within our control. We have no committed sources of additional capital at this time. Accordingly, we could exhaust our current cash resources prior to the identification or consummation of a suitable strategic alternative, requiring the Company to raise additional capital.

We anticipate that our exploration of strategic alternatives and advancing our obesity program will make it more difficult to raise additional capital. 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, which may further constrain our ability to execute on strategic alternatives.

We follow the guidance of Accounting Standards Codification, or ASC, Topic 205-40, *Presentation of Financial Statements - Going Concern*, in order to determine whether there is substantial doubt about our ability to continue as a going concern for one year after the date our financial statements are issued. Based on the current cash forecast, management has determined that our present capital resources will not be sufficient to fund our planned operations for at least one year from the issuance date of the financial statements, which raises substantial doubt as to our ability to continue as a going concern.

The forecast of cash resources is forward-looking information that involves risks and uncertainties, and our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, the progress of our strategic review and the pursuit of and progress on one or more options identified in such review. Global political and economic events, including the war in Ukraine and increased inflation, have already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital or make the terms of any available financing less attractive, which could in the future negatively affect our operations.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;

- unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any counterparty business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain our employee of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

If a strategic transaction is not consummated, our Board of Directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our Board of Directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations and exploration of strategic alternatives. In addition, if our Board of Directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board of Directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our remaining employee and consultants.

Our ability to consummate a strategic transaction depends upon our ability to retain our remaining employee and consultants, the loss of whose services may adversely impact our ability to consummate such transaction. In connection with the evaluation of strategic alternatives and in order to extend our resources, on August 14, 2023, we implemented the Plan that included reducing our workforce. The reduction in force has impacted approximately 95% of our workforce to date, including key members of our management team. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause our remaining employee and consultants to seek alternative opportunities. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could significantly disrupt our business.

On August 14, 2023, in connection with the evaluation of strategic alternatives and in order to extend our resources, our Board of Directors approved the Plan that included reducing our workforce, which has impacted approximately 95% of our workforce to date. In addition, the Plan included a discontinuation of our clinical development programs and further prioritization of our resources as we assess strategic alternatives. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, the Plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employee and consultants. Any employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of our employee and reduced productivity among the remaining employee and certain consultants of the Company. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, and commercial functions,

should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our product candidates. Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm the Company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, litigation, including securities class action litigation, has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC or other governmental agencies. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

RISKS RELATED TO OUR BUSINESS

****Although the monitoring period for our 2024 Delisting Determination from Nasdaq has closed, we remain at risk for delisting due to our volatile stock price and could then be subject to a new delisting notice from Nasdaq which could prevent us from maintaining an active, liquid and orderly trading market for our common stock and may materially and adversely impact our ability to consummate certain strategic transactions.***

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 Capital Market or if we are unable to transfer our listing to another stock market. On January 4, 2023, we were notified by The Nasdaq Stock Market LLC, or Nasdaq, that we were in breach of Listing Rule 5450(a)(1), or the Minimum Bid Price Rule, for continued listing on the Nasdaq Global Select Market because the minimum bid price of our listed securities for 30 consecutive business days had been less than $1 per share. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we were provided a period of 180 calendar days, or until July 3, 2023, or the Compliance Date, to regain compliance with the Bid Price Requirement. On June 22, 2023, we applied to transfer our listing from the Nasdaq Global Select Market to the Nasdaq Capital Market, or the Transfer. On July 5, 2023, Nasdaq notified us that the Transfer was approved, and that, in connection with the Transfer, we were eligible for an additional 180 calendar day period, or until January 2, 2024, or the Extended Compliance Date, to regain compliance with the Minimum Bid Price Rule.

On November 8, 2023, we received the Delisting Determination notifying us that, because the closing bid price for our common stock was below $0.10 per share for 10 consecutive trading days during the Extended Compliance Period, the Staff planned to suspend trading of our common stock as of November 17, 2023, and file a Form 25-NSE with the SEC to remove our common stock from listing and registration under the Securities Exchange Act of 1934, as amended, unless we timely request an appeal of the Delisting Determination to the Panel. After complying with Nasdaq's procedural requests and attending the required hearing, on February 16, 2024, we were notified by Nasdaq that we had regained compliance with the Minimum Bid Price Rule. We were then subject to a Mandatory Panel Monitor until February 16, 2025. We maintained compliance with the Minimum Bid Price Rule during the monitoring period, which ended February 16, 2025.

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 employee, 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. If our common stock is delisted from Nasdaq, trading in our securities may be subject to the SEC's "penny stock" rules. These "penny stock" rules will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities. Furthermore, if our common stock is delisted, we would expect it to have an adverse impact on our ability to consummate certain strategic alternatives.

Further, if our common stock is delisted, we would incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market.

****We do not have approval by our shareholders for a third reverse stock split of our common stock to enable the Board of Directors to respond to a Panel if we fail to comply with the Minimum Bid Price Rule in the future.***

While our stockholders approved a reverse stock split of the issued and outstanding shares of our common stock, our treasury stock, and a proportionate reduction in the shares of our authorized common stock, if needed in the discretion of our Board of Directors to regain compliance with the Minimum Bid Price Rule, at a ratio between the range of 1-for-5 and 1-for-15, inclusive, at any time on or before June 6, 2025, we executed this approved stock split to achieve compliance to the above-described delisting notice in July 2024. Therefore, if we receive another delisting notice before our 2025 annual stockholders meeting, we would have to convene a special shareholder meeting to obtain approval for another reverse stock split, should the Board decide to execute a reverse stock split in response to the delisting notice. There is no guarantee that the shareholders would approve another reserve stock split.

Shareholders may not approve another reverse stock split.

Even if we are able to convene a shareholders meeting within the time required by a future delisting notice, if received, there is no guarantee that the shareholders would approve a reverse stock split. Failure to acquire shareholder approval of a reverse stock split would negatively affect our ability to regain compliance with the Minimum Bid Price Rule, which would result in our common stock being delisted from the Exchange.

Even if we do get approval and effectuate a second reverse stock split, the trading price of our common stock may not meet the Minimum Bid Price Rule

If we do effect a reverse stock split in response to a future delisting notice, if received, there can be no assurance that the market price per new share of our common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of our common stock outstanding before the reverse stock split. Other factors, such as our financial results, market conditions and the market perception of our business may adversely affect the market price of our common stock and there can be no assurance that a reverse stock split, if completed, will result in the intended benefits, that the market price of our common stock will increase in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split or that the market price of our common stock will not decrease in the future. If the market price of our common stock does not increase the price per share of our common stock above Nasdaq's minimum bid price threshold of $1.00 per share or if the market price of our common stock does not remain above Nasdaq's minimum bid price threshold of $1.00 per share, our common stock may still be delisted from Nasdaq. There is also no guarantee that Nasdaq would agree that implementing a reverse stock split warrants would reverse the Staff's delisting determination, regardless of the price at which our common stock would trade following the split.

In light of our recent reverse stock splits, or if we implement another reverse stock split, liquidity of our common stock may be materially and adversely affected.

In light of our recent reverse stock splits, or if we have to effect another reverse stock split to avoid a delisting, the liquidity of the shares of our common stock may be materially and adversely affected by any such reverse stock split given the reduced number of shares of common stock that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split.

Following any reverse stock split, the resulting market price of our common stock may not attract new investors and may not satisfy the investing requirements of those investors. Although we believe a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

Since we effectuated a reverse stock split within the past year, should the trading price of our common stock fall again below the Minimum Bid Price requirement, we may be issued a delisting decision.

Under the recently amended Nasdaq reverse stock split rules, companies are limited by the number of times it can conduct a reverse stock split to regain compliance with the minimum bid price requirement. If a company's primary equity security fails to meet the minimum bid price requirement and the company has conducted a reverse stock split in the last year, it will not be eligible for any compliance period to address the price deficiency. If a company has effectuated a reverse stock split within the past year, and its security falls out of compliance with the minimum bid price requirement, it will be issued a delisting decision rather than receive a compliance period. We last effectuated a 10:1 reverse stock split in July 2024, and therefore may be subject to immediate delisting without being granted a compliance period should the trading price of our common stock fall below the minimum bid price requirement. There can be no assurance that the market price of our common stock will remain above the minimum bid price requirements even if we conduct another reverse stock split, and there can be no assurance of a positive outcome from an appeal of any delisting determination.

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

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

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

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

The development and commercialization of non-viral adoptive TCR-T cell therapies could be considered a new approach to cancer treatment, the successful development of which is subject to significant challenges.

We have employed technologies such as the technology licensed from MD Anderson pursuant to the MD Anderson License, described above, from Precigen, pursuant to the A&R License Agreement, and from the NCI, pursuant to the Patent License described above, to pursue the development and commercialization of non-viral cellular therapies based on T-cells and TCRs, targeting solid tumor malignancy. Because this is a new approach to cancer immunotherapy and cancer treatment generally, developing and commercializing product candidates is subject 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 the patient;
- developing and deploying consistent and reliable processes for engineering a patient's and/or donor's T-cells ex vivo and infusing the T cells back into the patient;
- conditioning patients with chemotherapy in conjunction with delivery of the potential products, which may increase the risk of adverse side effects of the chemotherapy itself or of the potential products;
- educating medical personnel regarding the potential side effect profile of each of the potential products, such as the potential adverse side effects related to cytokine release;
- addressing any competing technological and market developments;
- developing processes for the safe administration of these potential products, including long-term follow-up for all patients who receive the potential products;
- sourcing additional clinical and, if approved, commercial supplies for the materials used to manufacture and process the potential products;
- developing a manufacturing process with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance;
- developing therapies for types of cancers beyond those addressed by the current potential products;
- maintaining and defending the intellectual property rights relating to any products we develop;
- not infringing the intellectual property rights, in particular, the patent rights, of third parties, including competitors, such as those developing T-cell therapies; and

- unless we revoke the notice to terminate the Patent License or subsequently acquire substantially similar rights, our inability to use the technology currently licensed to us pursuant to the Patent License.

Should we resume our TCR-T clinical programs, 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. In addition, these challenges may diminish the value of our assets in the execution of any strategic alternative.

For our obesity program or, should we resume development of our TCR-T product candidates, we will need to recruit, hire and retain qualified personnel.

Following our strategic reprioritization in August 2023, we have reduced our workforce by approximately 95% to date. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause our remaining employee and consultants to seek alternative opportunities. The reductions in force included employees responsible for key aspects of our clinical and other development programs.

For our obesity program, or should we, in the future, resume development of our TCR-T product candidates, we may not be able to attract or retain qualified management and commercial, scientific, manufacturing and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

The termination of our licenses and research and development agreement with the National Cancer Institute and Precigen could significantly limit our ability to resume our clinical trial or begin new ones focused on TCR-T.

We have terminated our TCR licenses with the National Cancer Institute and Precigen. This will affect our ability to quickly resume TCR-T-based clinical trials as we will need to renegotiate these licenses or obtain approval from FDA to use TCRs that we have validated internally. We may not obtain such approval or be able to validate TCRs internally quickly or at all, significantly hindering our ability to resume our clinical trial.

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

Our clinical programs, if resumed, depend on patents, know-how, and proprietary technology that are licensed from others, particularly MD Anderson, 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 develop or monetize 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 Precigen, MD Anderson 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;
- 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 and Precigen, on acceptable terms, we may be unable to successfully monetize the affected potential products. Further, if we are unable to reacquire the rights from the NCI that we had under the Patent License prior to its termination, on terms acceptable to us or at all, our clinical development programs will be negatively impacted. 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 monetize 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 United States Patent and Trademark Office, or 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 Precigen by MD Anderson to technologies relating to TCR-T cell therapies and other related technologies.

Under the MD Anderson License, we, together with Precigen, received an exclusive, worldwide license to certain technologies owned and licensed by MD Anderson including technologies relating to novel 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 Precigen's technology suite and licensed to us by Precigen, 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 Precigen 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 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 or 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 or Precigen and may be terminated by the mutual written agreement of us, Precigen and MD Anderson.

Should we in the future resume development of our TCR-T product candidates, there can be no assurance that we will be able to successfully perform under the MD Anderson License or regain our terminated rights under the Patent License and if the MD Anderson License is terminated, we may be prevented from achieving our business objectives.

Should we resume development of our TCR-T product candidates, we may not be able to commercialize them, generate significant revenues, or attain profitability.

To date, none of our TCR-T 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. Should we resume clinical development, unless and until we receive approval from the FDA and/or other foreign regulatory authorities for our TCR-T product candidates, we cannot sell our products and will not have product revenues. Even if we should in the future resume development of our TCR-T product candidates and obtain regulatory approval for one or more of our TCR-T product candidates, if we are unable to successfully commercialize our TCR-T 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. If our preclinical obesity program is successful or we resume development of our TCR-T product candidates, 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.

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

Our contract research and development activities have involved and may in the future involve the controlled use of hazardous materials and chemicals. Although we believe that their safety procedures for using, storing, handling and disposing of these materials complied 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, results of operations, cash flows and prospects. 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, results of operations, cash flows and prospects.

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 throughout the US and other countries. 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.

****For our obesity assets, and should we in the future resume development of our TCR-T product candidates, will rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cybersecurity incidents, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability which could significantly harm our ability to operate our business effectively and adversely affect our business and reputation.***

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

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Any such event could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Although we have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates, we cannot guarantee that those measures will be successful in preventing any such security incident. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties. Such legal claims or proceedings, liability or government enforcement actions may make it more difficult to consummate

opportunities presented to us during our search for a strategic alternative. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to resume 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. 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 obesity, TCR-T or hunTR discovery engine were to experience a cyber-incident resulting in the disclosure or theft of our proprietary data, processes or procedures, their value may decrease and our business, or ability to consummate a strategic transaction, 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 search for a strategic alternative negatively impacted.

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

Our obesity assets are small molecules subject to the inherent difficulties in manufacturing small molecules for preclinical and clinical testing* in vitro*, animals and humans.

Our obesity assets are small molecules that are and will be manufactured *de novo* by third party CDMOs. Such manufacturing is potentially subject to complex synthesis processes that can be difficult to execute and expensive to conduct at either small scale for preclinical testing or large scale for clinical testing in humans, or both. Our manufactured small molecules may be subject to purity concerns that could impact both the drug's safety and efficacy. We are also susceptible to any future limited availability and supply chain disruptions of needed, critical raw materials which could affect our ability to manufacture sufficient materials needed for our testing and therefore delay clinical trials and commercialization.

Our reliance on third parties to formulate, manufacture and perform preclinical assays on our product candidates exposes us to a number of risks that may delay the development, regulatory approval and commercialization of our products or result in higher product costs.

We have limited experience in biopharmaceutical manufacturing. We currently lack the internal resources and expertise to formulate or manufacture our own small molecule product candidates and, therefore, contract the manufacture of these with third parties for use in *in vitro* and *in vivo* studies. We also intend to contract with one or more manufacturers to manufacture, supply, store, and distribute supplies for our clinical trials. In addition, we plan to use CDMOs, under our supervision, to perform our *in vitro* studies of the small molecules. If a product candidate we develop or acquire in the future receives FDA approval, we may also rely on one or more third-party contractors to manufacture our commercial products. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to at least the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor.
- The approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.
- Biopharmaceutical manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state and foreign agencies to ensure strict compliance with current good manufacturing practices, or cGMP, and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.
- Our future contract manufacturers may not perform as agreed or may remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Pharmaceutical manufacturers are subject to ongoing, periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state and foreign agencies to ensure strict compliance with current good manufacturing practices, or cGMP, and other government regulations and corresponding foreign standards. We do not have control over third party manufacturers' compliance with these regulations and standards.

- If any third party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovations.
- Our third party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United ed States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Each of these risks could delay our clinical trials and the approval, of the same,

Our obesity assets are in early, preclinical stage and may not produce the desired results in animals or in human subjects, if clinical trials are initiated.

Our obesity assets are small molecules that have not yet been tested or have been subject to limited testing in animals or humans. As we progress through pre-clinical to clinical stage assessments of these small molecules, it is possible that these small molecules have limited bioavailability wherein the drug is not effectively absorbed into the bloodstream, or once it has entered the bloodstream, the drug is rapidly broken down in the body before it is able to render the desired pharmaceutical effect in the patient, or that the drug is unable to timely reach the target(s) in sufficient concentrations to demonstrate efficacy.

Clinical trials are very expensive, time-consuming, and difficult to design, initiate and implement.

Human clinical trials are expensive and difficult to design, initiate and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial start-up and process itself is also time-consuming and results are inherently uncertain. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to delay the start of, abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- Additional nonclinical data requests by regulatory agencies;
- Unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- regulatory determinations to temporarily or permanently cease enrollment for other reasons not related to patient safety.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submission or in the conduct of these trials. Our business may be materially harmed if we or our partners are unable to adequately address the FDA's requests for this trial in a timely manner.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

Should we resume development of our TCR-T product candidates, we may encounter difficulties enrolling patients in our clinical trials, and our clinical development activities could be delayed or otherwise materially and adversely affected.

We have not yet begun to enroll patients for any obesity targeting clinical trial and we have experienced, and may in the future experience, difficulties in patient enrollment in our TCR-T Library Phase 1/2 Trial and any future clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

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

Should we resume clinical development of our TCR-T trial, they would compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition could 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 would expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use if we resume development of our product candidates, 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 or previously approved therapeutics for obesity or cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial. Additionally, because our TCR-T product candidates address patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial, which would require additional patient enrollment.

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

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

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

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

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

- Such authorities may disagree with the design or implementation of our or our 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 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, New Drug Application, 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 should we resume clinical development, which would significantly harm our business, financial condition, results of operations, cash flows and prospects. In addition, even if we obtain regulatory approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request and may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS.

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

We have halted development of our TCR-T product candidates very early in our development efforts. Our most advanced product candidates were only in an early-stage clinical trial, which is very expensive and time-consuming while our obesity assets have not yet completed* in vitro *testing. We cannot be certain if or when we will be able to submit a BLA or an NDA to the FDA and the delay, or any failure, in completing clinical trials for our product candidates could significantly harm our business.

Our obesity assets have not yet completed *in vitro* testing while our most advanced TCR-T product candidates were only in a Phase 1/2 trial when we ceased development activity and will require extensive clinical testing should we resume development. Human clinical trials are very expensive and difficult to design, initiate and implement, in part because they are subject to rigorous regulatory requirements. 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, if resumed, include: requests for additional nonclinical data from regulators, unforeseen safety issues, dosing issues, lack of effectiveness during clinical trials, difficulty recruiting or monitoring patients, or difficulty manufacturing clinical products, among other factors.

As they enter later stages of development, 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 or any potential licensee 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, the ability to further develop, or seek approval for, such product candidates may

be materially impacted. As such, for our obesity asset or if we resume clinical development of our TCR-T product candidates, we cannot predict with any certainty if or when we might submit a NDA or biologics license application or BLA for regulatory approval of our product candidates or whether such NDA or BLA will be accepted. Because we do not anticipate generating significant revenues unless and until we submit one or more NDAs or BLAs and thereafter obtain requisite FDA approvals, the timing of our NDA and BLA submissions and FDA determinations regarding approval thereof will directly affect if and when we are able to generate significant revenues.

In addition, we have halted development of our TCR-T product candidates. There is an additive degree of risk to any development program that is paused because the time to restart the program and the associated expense may be longer and more costly than previously anticipated. It may also not be possible to restart the program altogether.

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, if resumed, may produce undesirable side effects or adverse reactions or events, including, with respect to our TCR-T product candidates, 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, should we resume it. The FDA or foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. If a serious adverse event were to occur in a 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 resume and 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. Should we resume product development or begin commercialization, we expect to have to train medical personnel using our product candidates to understand their side effect profiles. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in adverse effects to patients, including death. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our product candidates, a number of potentially significant negative consequences could result, including:

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

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

Our cellular therapy immuno-oncology TCR-T product candidates relied 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 if we resume our clinical trial. For some of these reagents, equipment and materials, we relied or may rely on sole source vendors or a limited number of vendors, which could significantly impair our ability to manufacture and supply our products, should we resume these activities.

Manufacturing our TCR-T product candidates required 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 have depended on a limited number of vendors for certain materials and equipment used in the manufacture of our TCR-T product candidates, including DNA plasmids, which we used as the vector to insert our TCRs into human T cells. Should we resume product manufacturing, some or all 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, should we resume manufacturing. We also do not have supply contracts with some of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience significant delays in receiving key materials and equipment to support clinical or commercial manufacturing, should we resume those activities.

For some of these reagents, equipment, infrastructure, and materials, we may rely on sole source vendors or a limited number of vendors. An inability to source product from any of these suppliers, or source product on commercially reasonable terms, which could be due to, among other things, regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, supply chain issues or quality issues, could materially and adversely affect our ability to satisfy

demand for our product candidates, which could adversely and materially affect our ability to conduct clinical trials, should we resume them, which could significantly harm our business.

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

If we resume developing and scaling 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 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.

We have limited experience producing and supplying our TCR-T product candidates. We may be unable to consistently manufacture our TCR-T product candidates to the necessary specifications or in quantities necessary to treat patients in clinical trials, should we resume the activities.

We have limited experience in biopharmaceutical manufacturing. In 2021, we began manufacturing our product candidates at our in-house current good manufacturing practices, or cGMP, manufacturing facility at our leased headquarters in Houston, Texas. In connection with our exploration of strategic alternatives, we have halted manufacturing of our product candidates and eliminated positions relating to the same. We have also permanently closed our Houston manufacturing facility as of November 2023 as a part of our lease termination. Accordingly, should we elect to in the future, our ability to resume manufacturing our product candidates will depend on our acquisition of new manufacturing space. hiring and retaining personnel with the appropriate background and training to staff and operate the facility on a daily basis. Should we be unable to hire or retain these individuals, we may need to train additional personnel to fill the needed roles or engage with external contractors. There are a small number of individuals with experience in cell therapy and the competition for these individuals is high.

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

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. It is possible that stability or other issues relating to the manufacture of our product candidates could occur in the future. Before we halted clinical development, we had amended our clinical trial IND to use cryopreservation-based storage of clinical products. This process is new and should we resume clinical development and in-house manufacturing, we may experience manufacturing failures or difficulties producing sufficient quantities of our clinical products as a result of this change.

Our TCR-T product candidates have been manufactured on a patient-by-patient basis. Delays in manufacturing could adversely impact the treatment of each patient and may discourage participation in clinical trials should clinical development be resumed. We have not 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, should development resume in the future. 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, development efforts would be delayed, which would adversely affect our business and prospects.

Manufacturing operations are subject to review and oversight by the FDA. If we resume internal manufacturing operations, 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 cGMP and other government regulations. Our license to manufacture product candidates is subject to continued regulatory review.

We do not yet have sufficient information to reliably estimate the cost of commercial manufacturing and processing of our product candidates. The actual cost to manufacture and process our product candidates 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, should we resume the trial.

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

During our development of the manufacturing process, our TCR-T cell product candidates have demonstrated consistency from lot to lot and from donor to donor. However, our sample size is small and the starting material used during our preclinical development work came from healthy donors. If our development work is continued, 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 TCR-T manufacturing process is scalable for clinical development and commercialization, if any of our product candidates are approved or commercialized, we may encounter challenges in validating our process due to the heterogeneity of the product starting material. We cannot guarantee that any other issues relating to the heterogeneity of the starting material will not impact our ability to commercially manufacture our product candidates.

The gene transfer vectors from our* Sleeping Beauty *system used to manufacture our TCR-T 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 were manufactured using the *Sleeping Beauty* system, a non-viral vector to insert genetic information encoding the TCR construct into the patient's T cells. The TCR construct was 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 used non-viral vectors to insert genetic information into T cells, which we believe have a lower risk of insertional oncogenesis as opposed to viral vectors. However, the risk of insertional oncogenesis remains a concern for gene therapy, and we cannot assure you that it will not occur in any clinical trials of our product candidates. 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 our product candidates 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, preclinical studies or clinical trials could be halted or delayed, which would have a material adverse effect on our business and operations.

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

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

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

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

- Litigation involving patients taking our products;
- 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.

Disruptions at the FDA, the SEC, and other government agencies caused by funding shortages or personnel changes could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations rely, including those that fund research and development activities, is subject to the political process, which is fluid and unpredictable.

Furthermore, the risk of a protracted government shutdown could adversely affect our business. Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, like the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it would significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future government shutdowns could also impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

Our inability to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate would cause our business to suffer significantly.

For our obesity assets, and if we resume clinical development of our TCR-T product candidates, 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 NDA or BLA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the product candidate, and will require substantial resources for research, development and testing. We cannot predict whether our research, development, and clinical approaches will result in products that the FDA will consider safe for humans and effective for their intended uses. The FDA has substantial discretion in the approval process and may require us to conduct additional preclinical studies and clinical trials or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation,

future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

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

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs or 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. We anticipate allocating resources to the marketing, sales and distribution of our proposed small molecule products, as well as our TCR-T product candidates if we resume work on these, in North America and in certain other geographies; however, we cannot assure that we will be able to market, sell, and distribute our products successfully. Our future success also may depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities and to encourage the collaborator's strategic interest in the product candidates under development, and such collaborator's ability to successfully market and sell any such products. Although we intend to pursue certain collaborative arrangements regarding the sale and marketing of certain of our product candidates, there are no assurances that we will be able to establish or maintain collaborative arrangements or, if we are able to do so, whether we would be able to conduct our own sales efforts. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product candidates in the United States or overseas.

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

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

Even if the FDA and/or foreign equivalents thereof approve our product candidates, physicians and patients may not accept and use them. The use of engineered T cells as potential cancer treatments is a relatively recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers for our TCR-T products, 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.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

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

Our ability to commercialize our product candidates, if approved, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement will be available from third-party payors, including government and health administration authorities, private health maintenance organizations and health insurers and other payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Sufficient coverage and adequate reimbursement from third-party payors are critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. It is difficult to predict the coverage and reimbursement decisions that will be made by third-party payors for novel gene and cell therapy products such as ours. Even if we obtain coverage for our product candidates, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates.

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

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

In addition, in many foreign countries, particularly the countries of the European Union, or 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 TCR-T product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

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

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

Our projections of both the number of people who have the cancers we targeted, 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.

Several drugs have already been approved for diabetes and/or obesity treatment, which may affect our ability to gain a profitable share of the market.

Even if our obesity assets are approved by FDA and successfully launched as a commercial product, the market may be saturated by previously approved drugs that have been demonstrated to be effective in treating obesity already, making the market difficult to penetrate. The availability of previously approved drugs may also limit the availability of insurance reimbursement/coverage of our product candidates.

Healthcare legislative reform measures may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

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

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

There have been executive, legal and political challenges to certain aspects of the ACA. For example, President Trump signed several executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, Congress repealed the tax penalty, effective January 1, 2019, for an individual's failure to maintain ACA-mandated health insurance as part of the Tax Act. The IRA, among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and implementing a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future, particularly in light of the Trump administration's interest in reducing federal expenditures to include those under federal healthcare programs. It is unclear how any such challenges of the Trump administration will impact ACA and our business. The ultimate content, timing or effect of any healthcare reform measures on the U.S. healthcare industry is unclear.

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

The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 30, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2032. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, which was set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. The IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through

guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Individual states in the United States also have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

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

ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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

Efforts to ensure that our business arrangements comply with applicable healthcare laws involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in United States federal or state health care programs, such as Medicare and Medicaid, disgorgement, imprisonment, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

The Hatch Waxman Act provides a pathway for companies to gain entry to the market for certain small molecule-based drugs more quickly and less expensively than brand companies. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, provides a similar 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. The entry of a generic or biosimilar to our product candidates to the market would significantly affect our profitability and return on investment.

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 develop our product candidates may be materially 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. Our ability to consummate certain strategic transactions, including strategic partnerships or out-licensing opportunities, among others, may also be impaired if we are unable to adequately protect our intellectual property or if we infringe on the proprietary rights of others.

To date, we have maintained our TCR-T related patent portfolio including those 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 licensed from MD Anderson. Under the MD Anderson License, future patent applications require the agreement of each of MD Anderson, Precigen 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 Precigen instead may control such activities. Although under the License Agreement MD Anderson has agreed to review and incorporate any reasonable comments that we or Precigen may have regarding licensed patents and patent applications, we cannot guarantee that our comments will be solicited or implemented. Without direct control of the in-licensed patents and patent applications, we are dependent on MD Anderson or Precigen, as applicable, to keep us advised of prosecution, particularly in foreign jurisdictions where prosecution information may not be publicly available. We anticipate that we will file additional patent applications both in the United States and in other jurisdictions on all of our product candidates. However, we cannot predict or guarantee for either our in-licensed patent portfolios or for Alaunos' proprietary 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 or Precigen, to the extent not then terminated, 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 significantly 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 employee, 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 currently license from MD Anderson and Precigen is early-stage technology, and we were in the process of designing and developing products using this technology. Although we sought and, should we resume development activities, will seek to avoid pursuing the development of products that may infringe any third-party patent claims that we believe to be valid and enforceable, we may fail to do so. Moreover, given the breadth and number of claims in patents and pending patent applications in the field of immuno-oncology and the complexities and uncertainties associated with them, third parties may allege that we are infringing patent claims even if we do not believe such claims have merit.

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

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

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

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

Annuities and other similar fees must be paid to the respective patent authority to maintain patents (or patents and patent applications) in most jurisdictions worldwide. Further, patent authorities in jurisdictions worldwide require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events

that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to submit documents with the necessary formal requirements, such as notarization and legalization. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

Any failure by us to obtain a needed license, comply with any of these obligations or any other breach by us of our license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. 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, cash flows and prospects.

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

Many of our former 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 former employees and our current employee does 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 employee 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, should we resume clinical development;
- The commencement, enrollment or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;

- Public statements by third parties like trial participants and clinical investigators regarding clinical trials;
- Public concern as to the safety of drugs developed by us or others;
- The financial or operational projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- Comments by securities analysts or changes in financial estimates or ratings by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- The public's response to press releases or other public announcements by us or third parties, including our filings with the SEC, as well as announcements of the status of development of our products, announcements of technological innovations or new therapeutic products by us or our competitors, announcements regarding collaborative agreements and other announcements relating to product development, litigation and intellectual property impacting us or our business;
- Government regulation;
- FDA determinations on the approval of a product candidate NDA or 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 removal from certain stock indices;
- Our delisting from Nasdaq;
- Developments in patent or other proprietary rights;
- Changes in reimbursement policies;
- Announcements of medical innovations or new products by our competitors;
- Announcements of changes in our senior management or directors;
- General economic, industry, political and market conditions, including, but not limited to, the ongoing impact of global economic conditions;
- Other events or factors, including those resulting from war, incidents of terrorism, natural disasters, pandemics or responses to these events; and
- Changes in accounting principles.

In addition, the stock market in general and our stock in particular from time to time experiences significant price and volume fluctuations unrelated to the operating performance of particular companies, 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 Capital Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many biopharmaceutical companies.

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

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

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.

We have begun exploring strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions. If we are approached by a third-party in connection with such process, and our Board of Directors does not believe that a transaction with such party is in the best interest of our stockholders, we may rely on the provisions described above to prevent an acquisition by such party in order to maximize stockholder value. There is no guarantee that we will be able to find a transaction that delivers superior value to our stockholders.

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

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

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

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

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

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

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

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

If securities' and/or industry analysts' recommendations change adversely or if our business, financial condition, results of operations, cash flows or prospects do not meet their expectations, our stock price and trading volume could significantly 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 business, financial condition, results of operations, cash flows or prospects do not meet their expectations, our stock price could significantly decline. If our common stock is delisted by Nasdaq, the impact of analysts ceasing to cover our securities may negatively impact the price of our common stock more dramatically.

Our business could be materially and 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 stockholders 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.

If our Board of Directors elects to pursue a strategic alternative requiring a stockholder vote, activists may pursue a campaign against the transaction and as a result may make consummating the transaction more difficult, or impossible, despite the Board of Directors' conclusions that such transaction is in the best interest of our stockholders.

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 significantly harm the market price of our common stock.

As of December 31, 2024, our executive officers, directors and holders of five percent or more of our outstanding common stock beneficially owned, in the aggregate, 3.45% 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.

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 business, financial condition, results of operations, cash flows and prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million as of the last business day of our most recently completed second quarter if our annual revenues are $100 million or more as of our most recently completed fiscal year, or until our public float exceeds $700 million as of the last business day of our most recently completed second quarter if our annual revenues are less than $100 million as of our most recently completed fiscal year.

****Artificial intelligence used by us and our partners and vendors may have negative effects on our company.***

Artificial intelligence or AI use in many industries has rapidly expanded. While we do not utilize any specific AI technologies internal to Alaunos, we may work with vendors or service providers that do utilize AI technologies with or without our knowledge. Areas in which our business that could be negatively impacted include novel cybersecurity threats such as malicious code or phishing attempts. AI could also perpetrate fraud or misappropriation of company funds. From a regulatory standpoint, we could be liable for noncompliance related to data compromise or perceived or actual noncompliance with data privacy or protection or AI requirements to various agencies or jurisdictions. There are also potential risks around ethical, social, and reputational risks should AI cause us to infringe on privacy rights or violate intellectual property rights. AI is also known for "deep fakes" or false information being spread electronically and attributed to innocent companies and their management or directors. Such accusations could negatively impact human rights, privacy, employment, or other social concerns, which may result in claims, lawsuits, brand or reputational harm, and increased regulatory scrutiny, any of which could harm our business, financial condition, and operating results. Operational risks potentially caused by AI technologies include unanticipated disruptions to systems, potential loss or corruption of data, implementation delays, and cost overruns that could stem from underlying defects in the AI tools used. Finally, competition risk may result from rapid adoption of AI that could provide unforeseen advantages to our competitors and lead to the erosion of our market share by potentially leading to the emergence of new products and categories, the rapid maturation of categories, cannibalization of categories, changing price points and product replacement and upgrade cycles.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Program

We have implemented a cybersecurity program to support both the effectiveness of our systems and our preparedness for information security risks. This program includes a number of safeguards, such as: password protection; multi-factor authentication; monitoring and alerting systems for internal and external threats; and regular evaluations of our cybersecurity program.

We use a risk-based approach with respect to our use and oversight of third-party service providers, tailoring processes according to the nature and sensitivity of the data accessed, processed, or stored by such third-party service provider. We also seek to include appropriate security terms in our contracts, where applicable as part of our oversight of third-party providers.

Process for Assessing, Identifying and Managing Material Risks from Cybersecurity Threats

We maintain an incident response program. In the event of a cybersecurity incident, designated personnel are responsible for assessing the severity of an incident and associated threat, containing the threat, remediating the threat, including recovery of data and access to systems, analyzing any reporting obligations associated with the incident, and performing post-incident analysis and program enhancements. We maintain an Incident Response Plan, which includes an Incident Response Process in the event of a significant cybersecurity incident. In the event of a significant cybersecurity incident, our head of administration will chair an incident response team to handle the incident. Such incident response team will include members of IT, finance (if applicable), legal, communications, human resources and any affected unit or department. IT, along with a designated forensic team, will use the Incident Response Process to guide the response.

Governance

Management Oversight

The controls and processes employed to assess, identify and manage material risks from cybersecurity threats are implemented and overseen by head of administration and our managed service provider. Our head of administration has over four years of experience addressing cybersecurity risks. Our head of administration is responsible for the day-to-day management of the cybersecurity program, including the prevention, detection, investigation, response to, and recovery from cybersecurity threats and incidents, and is regularly engaged to help ensure the cybersecurity program functions effectively in the face of evolving cybersecurity threats. Our head of administration oversees the Incident Response Plan and briefs our board of directors on cybersecurity matters, including the nature and design of our cybersecurity program, and threats, events, and program enhancements.

Board Oversight

In its oversight role, our Board of Directors is expected to specifically consider risks, including with respect to privacy, information technology and cybersecurity and threats to technology infrastructure.

On a regular basis, the head of administration reports to our Board of Directors on cybersecurity matters, including key risks, the potential impact of those exposures on our business, financial condition, results of operations, cash flows and prospects, and the programs and steps implemented by our management team to monitor and mitigate risks.

Cybersecurity Risks

Our cybersecurity risk management processes are integrated into our overall approach to risk management. Given our nature and size, we do not have a dedicated enterprise risk function, but our management team regularly considers and evaluates risks. As part of that risk management

process, our management team identifies, assesses and evaluates risks impacting our operations, including those risks related to cybersecurity, and raise them for internal discussion, and where it is determined to be appropriate, issues are also raised to our Board of Directors for consideration.

As of the date of this Annual Report on Form 10-K, we are not aware of any previous cybersecurity incidents that have materially affected our business, financial condition, results of operations, cash flows and prospects or that are reasonably likely to have such a material effect. While we have implemented a cybersecurity program, the techniques used to infiltrate information technology systems continue to evolve. Accordingly, we may not be able to timely detect threats or anticipate and implement adequate security measures. For additional information regarding risks relating to privacy and cybersecurity, see "Item IA—Risk Factors—Risks Related to Our Business."

Item 2. Properties

Our corporate office is located at 2617 Bissonnet Street, Suite 233, Houston, Texas 77005. 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 business, financial condition, results of operations, cash flows and prospects. In addition, regardless of the outcome, litigation could have a material and 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, be reasonably likely to have a material adverse effect on our business, financial condition, results of operations, cash flows or prospects.

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 Capital Market under the symbol "TCRT."

Record Holders

As of March 31, 2024, we had approximately 129 holders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company, or DTC. Shares of common stock that are held by financial institutions as nominees for beneficial owners or in "street name" are deposited into participant accounts at DTC and are considered to be held of record by Cede & Co. as one stockholder.

Dividends

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

Unregistered Sales of Securities

We did not sell or issue any equity securities during the three months ended December 31, 2024 that were not registered under the Securities Act.

Repurchases

There were no repurchases of our common stock by the Company during the fiscal quarter ended December 31, 2024.

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, levels of activity, performance or achievements 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. All share amounts presented in this Item 7 give effect to the 1-for-15 reverse stock split and the 1-for-10 second reverse stock split of our outstanding shares of common stock that occurred on January 31, 2024 and July 17, 2024, respectively.

Overview

On October 10, 2024, we announced our continued progress and evaluation of our internally developed small molecule oral obesity program. The aim of this program is to develop a drug for obesity with a differentiated profile relative to currently marketed and in development oral and injectable products. We have also operated as a clinical-stage oncology-focused cell therapy company developing adoptive TCR-T cell therapy, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. On August 14, 2023, we announced a strategic reprioritization of our business and wind down of our TCR-T Library Phase 1/2 Trial. In connection with the reprioritization, we have reduced our workforce during the third and fourth quarters of 2023, and we continue working to reduce costs in order to extend our cash runway. We continue to explore strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions. We engaged Cantor Fitzgerald & Co., or Cantor, to act as strategic advisor for this process.

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, 2024, we had a net loss of $4.6 million, and as of December 31, 2024, we have incurred approximately $920.4 million of accumulated deficit since our inception in 2003. We expect to continue to incur significant operating expenditures and net losses for the foreseeable future.

2024 Developments

Obesity Program

On October 10, 2024, we announced our continued progress and evaluation of our internally developed small molecule oral obesity program. The aim of this program is to develop an oral drug for obesity and other metabolic disorders with a differentiated profile relative to currently marketed and in development oral and injectable products. We believe our small molecule product candidates are distinct in that they do not rely on hormonal manipulation, which is common with many obesity treatments. We aim to develop an oral obesity compound that addresses many of the shortcomings of injectable GLP-1 receptor agonists including preserving lean muscle mass. We engaged a contract development and manufacturing organization or CMDO to manufacture active pharmaceutical ingredients for our small molecule product candidates and initiated *in vitro* testing of our candidates in the fourth quarter 2024.

The ongoing *in vitro* study aims to evaluate the impact of ALN1001 and its derivatives on lipid deposition and gene expression. This study evaluates if genes related to thermogenic activity, lipid metabolism, and energy regulation are activated or deactivated by treatment, to determine if these compounds positively affect fat and energy metabolism. The results of this study, which are expected early second quarter of 2025, will provide critical insights into the development strategy for ALN1001 and its derivatives for obesity, metabolic disorders, and inflammation. Drug development candidates most effective in increasing metabolic activity and reducing fat accumulation may be advanced to evaluation of the compounds in rodent models of obesity.

As is standard in the industry, if the aforementioned *in vitro* study is successful, we plan to conduct a proof-of-concept diet-induced obesity or DIO mouse study to validate our mechanism of action by the third quarter of 2025 before proceeding to Investigational New Drug or IND Application enabling studies. Our ability to execute on this plan is dependent on study results and our ability to raise additional capital or partner these assets with other companies or research institutions.

TCR-T Library Phase 1/2 Trial

Eight patients were treated and evaluated in our TCR-T Library Phase 1/2 Trial from 2022-2023. Patients with pancreatic (3), colorectal (4) and non-small cell lung cancer (1) were treated, with certain pancreatic and colorectal patients also having lung metastases. Overall, the trial showed our T-cells were generally well-tolerated in all evaluable participants with no dose-limiting toxicities (DLTs) and no immune effector cell-associated neurotoxicity syndrome (ICANS) were observed. All cytokine release syndrome (CRS) events were within grades 1-3 and were self-limiting or resolved with standard clinical management and, in some cases, a single dose of tocilizumab. One patient with non-small cell lung cancer (NSCLC) achieved an objective partial response with six months progression-free survival. Six other patients achieved a best overall response of stable disease. The total overall response rate was 13% and disease control rate was 87% in evaluable patients with advanced, metastatic, refractory solid tumors (see Figure A). This trial established proof-of-concept that Sleeping Beauty TCR-T cells can result in objective clinical responses and recognize established tumors *in vivo*. Despite the encouraging TCR-T Library Phase 1/2 Trial data, based on the substantial

cost to continue development and the current financing environment, we announced in August 2023 that we would not pursue any further development of our clinical programs.

hunTR® Platform

We have discovered multiple proprietary TCRs targeting driver mutations through our hunTR TCR discovery platform. In addition to TCRs that recognize KRAS and TP53 mutations similar to those licensed from the NCI, we identified additional TCRs that bind to other driver mutations and TCRs that are restricted to additional HLAs. We believe that the hunTR library has the potential to allow for the treatment of a large patient population.

Strategic Alternatives

We continue to explore strategic alternatives, which may include but are not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions.

Nasdaq Delisting Determination

As previously disclosed on January 4, 2023, we were notified by the Listing Qualifications Department, or the Staff, of 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 were provided a period of 180 calendar days, or until July 3, 2023, or the Compliance Date, to regain compliance with the Bid Price Requirement. On June 22, 2023, we applied to transfer our listing from the Nasdaq Global Select Market to the Nasdaq Capital Market, or the Transfer. On July 5, 2023, Nasdaq notified us that the Transfer was approved, and that, in connection with the Transfer, we were eligible for an additional 180 calendar day period, or until January 2, 2024, or the Extended Compliance Date, to regain compliance with the Minimum Bid Price Rule. On November 8, 2023, we received a Staff Delisting Determination letter, or the Delisting Determination, from the Staff notifying us that, because the closing bid price for our common stock was below $0.10 per share for 10 consecutive trading days during the Extended Compliance Period, the Staff has determined to suspend trading of our common stock on Nasdaq pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(iii), effective November 17, 2023, and file a Form 25-NSE with the SEC to remove our common stock from listing and registration under the Securities Exchange Act of 1934, as amended, unless we timely request an appeal of the Delisting Determination to a Nasdaq Hearings Panel, or the Panel. We timely requested a hearing before the Panel to appeal the Delisting Determination and were granted a hearing before the Panel on January 25, 2024. This timely request for a hearing stayed the suspension or delisting of our common stock so our common stock continued to trade on the Nasdaq Capital Market under the symbol “TCRT” while the appeal process was pending. By letter dated February 16, 2024, we were notified by the Nasdaq Stock Market LLC that we regained compliance with the minimum $1.00 bid price requirement, and otherwise satisfied all applicable criteria for continued listing on the Nasdaq Capital Market. As such, the listing matter was closed. Pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we were subject to a mandatory panel monitor for the one-year period which was completed on February 16, 2025.We are no longer subject to monitoring by the panel.

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 have historically consisted 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, or CROs, in conjunction with clinical trials, fees paid to CROs in conjunction with costs of materials used in research and development, consulting, license and milestone payments, sponsored research fees paid to third parties and impairment charges to prepaid expenses and other current assets.

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.

Restructuring Costs

Restructuring costs consists of severance provided to terminated employees.

Other Income (Expense)

Other income (expense) consists primarily of interest expense associated with our amended Loan and Security Agreement, interest income on our cash balances and sublease income.

Results of Operations for the Fiscal Years ended December 31, 2024 and 2023

($ in thousands)	Year Ended December 31, 2024	2023
Revenue	$ 10	$ 5
Operating expenses:		
Research and development	362	16,279
General and administrative	4,460	12,219
Gain on lease modification and termination	-	(298)
Restructuring costs	-	1,269
Property and equipment and right-of-use assets impairment	-	4,803
Total operating expenses	4,822	34,272
Loss from operations	(4,812)	(34,267)
Other income (expense):		
Interest expense	-	(1,921)
Other income (expense), net	133	1,048
Other income (expense), net	133	(873)
Net loss	$ (4,679)	$ (35,140)

Revenue

Revenue during the years ended December 31, 2024 and 2023 were as follows:

($ in thousands)	Year Ended December 31, 2024	2023	Change	
Revenue	$ 10	$ 5	$ 5	100%

Revenue during the year ended December 31, 2024 was $10 thousand compared to $5 thousand during the year ended December 31, 2023.

Research and Development Expenses

Research and development expenses during the years ended December 31, 2024 and 2023 were as follows:

($ in thousands)	Year Ended December 31, 2024	2023	Change	
Research and development expenses	$ 362	$ 16,279	$ (15,917)	(98)%

Research and development expenses for the year ended December 31, 2024 decreased by $15.9 million when compared to the year ended December 31, 2023 primarily due to lower program expenses of $8.5 million as a result of the wind down of our clinical activities, a $4.5 million decrease in employee-related expenses due to our reduced headcount, an accrual adjustment related to our de-prioritized clinical programs of $0.2 million, a $2.5 million decrease in facilities costs following the termination of our leases.

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, which we are still in the process of winding down due to various closing processes and follow up studies that are required before the project can be shut down permanently.

General and Administrative Expenses

General and administrative expenses during the years ended December 31, 2024 and 2023 were as follows:

($ in thousands)	Year Ended December 31, 2024	2023	Change	
General and administrative expenses	$ 4,460	$ 12,219	$ (7,759)	(63)%

General and administrative expenses for the year ended December 31, 2024 decreased by $7.7 million as compared to the year ended December 31, 2023, primarily due to a $7.5 million decrease in consulting and employee-related expenses as a result of our reduced headcount and a $0.2 million decrease in facility cost due to the reduction in depreciation expenses and rent as a direct result of the lease termination in the prior period.

Gain on lease modification and termination

Gain on lease modification and termination during the years ended December 31, 2024 and 2023 was as follows:

	Year Ended December 31,		Change	
($ in thousands)	**2024**	**2023**		
Gain on lease modification and termination	$ —	$ (298)	$ 298	(100)%

Gain on lease modification and termination during the year ended December 31, 2023 was $0.3. As a result of real estate lease terminations during 2023, the associated lease liabilities and right-of-use assets were remeasured based on the revised lease payments, resulting in a gain of $0.3 million.

Restructuring costs

Restructuring costs during the years ended December 31, 2024 and 2023 were as follows:

	Year Ended December 31,		Change	
($ in thousands)	**2024**	**2023**		
Restructuring costs	$ —	$ 1,269	$ (1,269)	(100)%

Restructuring costs during the year ended December 31, 2024 were $0 million as compared to $1.3 during the year ended December 31, 2023, due to severance expenses for terminated employees related to our strategic reprioritization announced in August 2023.

Impairments

Impairments during the years ended December 31, 2024 and 2023 were as follows:

	Year ended December 31,		Change	
($ in thousands)	**2024**	**2023**		
Property and equipment and right-of-use assets impairment	$ —	$ 4,803	$ (4,803)	100%

Property and equipment and right-of-use asset impairments of $0 million were recorded during the year ended December 31, 2024, compared to $4.8 during the year ended December 31, 2023, following the announcement of our strategic reprioritization in August 2023.

Other Income (Expense)

Other income (expense) during the years ended December 31, 2024 and 2023 was as follows:

	Year Ended December 31,		Change	
($ in thousands)	**2024**	**2023**		
Interest expense	$ —	$ (1,921)	$ 1,921	(100)%
Other income, net	133	1,048	(915)	(87)%
Total	$ 133	$ (873)	$ 1,006	(115)%

Total other income (expense), net for the year ended December 31, 2024 increased by $1.00 million as compared to the year ended December 31, 2023 primarily due to no interest expense associated with our former amended Loan and Security Agreement.

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.

On August 14, 2023, we announced a strategic reprioritization of our business and wind down of our TCR-T Library Phase 1/2 Trial. In connection with the reprioritization, we have reduced our workforce, and we continue working to reduce costs in order to extend our cash runway. We continue to explore strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions. We engaged Cantor to act as strategic advisor for this process.

We follow the guidance of Accounting Standards Codification, or ASC, Topic 205-40, *Presentation of Financial Statements - Going Concern*, in order to determine whether there is substantial doubt about our ability to continue as a going concern for one year after the date our financial statements are issued. Given our current development plans and cash management efforts, we anticipate that our cash resources will be sufficient to fund operations into the second quarter of 2025. Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in our focus and direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If adequate additional funds are not available when required, management may need to curtail its development efforts and planned operations to conserve cash.

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

Cash Flows

The following table summarizes our net increase (decrease) in cash and cash equivalents for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
($ in thousands)	**2024**	**2023**
Net cash flows in:		
Operating activities	$ (4,971)	$ (30,142)
Investing activities	—	1,346
Financing activities	—	(18,138)
Net decrease in cash and cash equivalents	$ (4,971)	$ (46,934)

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, amortization, impairment charges, stock-based compensation and reduction in right-of-use assets; 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, 2024 was $5.0 million, as compared to $30.1 million for the year ended December 31, 2023. The net cash used in operating activities for the year ended December 31, 2024 was primarily a result of our net loss of $4.6 million, adjusted for $4.7 million of non-cash items such as depreciation, property and equipment and right-of-use assets impairment, stock-based compensation and a $2.8 million decrease in accrued expenses, a decrease in accounts payable of $0.6 million, a decrease of $1.4 million in prepaid expenses and $0.5 million decrease in other current assets and accounts receivables of $7 thousand.

Net cash provided by investing activities was $0 million for the year ended December 31, 2024 as compared to net cash provided in investing activities of $1.3 million for the year ended December 31, 2023. The decrease is related to no investing activities during the current period as compared to the prior period.

Net cash used in financing activities was $0 million for the year ended December 31, 2024 compared to $18.1 million of net cash used by financing activities for the year ended December 31, 2023. The decrease was primarily related to the repayment of long-term debt in 2023 that did not recur in 2024.

Operating Capital and Capital Expenditure Requirements

We anticipate that losses will continue for the foreseeable future. As of December 31, 2024, our accumulated deficit was approximately $920.4 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, including those resulting from the recently announced exploration of strategic alternatives and related workforce reduction.

As of December 31, 2024, we had approximately $1.1 million of cash and cash equivalents. Our streamlined and cost efficiency efforts, in light of our 2023 announced strategic reprioritization , we anticipate our cash resources will be sufficient to fund our operations into the second quarter of 2025. In order to continue our operations beyond our forecasted runway, including, if necessary, to continue to explore strategic alternatives, 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, we may be unable to persist as a going concern for sufficient time to identify or execute on any strategic alternatives.

Operating Leases

As of December 31, 2024, we have no lease commitments, other than a short-term lease.

Royalty and License Fees

On May 28, 2019, the Company entered into a Patent License with the NCI for exclusive worldwide rights to develop and commercialize certain engineered T-cell therapies targeting mutated KRAS, TP53, and EGFR neoantigens, as well as related manufacturing technologies. The agreement included minimum annual royalties, milestone payments upon achieving clinical, regulatory, and sales benchmarks, and royalties on product sales. The Company terminated the agreement effective December 26, 2023, after developing proprietary alternatives internally. The Company incurred no expenses under this agreement in 2024, compared to $0.3 million in 2023.

In June 2022, Solasia Pharma K. K., or Solasia, announced that darinaparsin had been approved from relapsed or refractory Peripheral T-Cell Lymphoma by the Ministry of Health, Labor and Welfare in Japan. During the year ended December 31, 2024, the Company did not earn collaboration revenue and earned $10 thousand in royalty revenues on net sales under the Solasia License and Collaboration Agreement. During the year ended December 31, 2023, the Company did not earn collaboration revenue and earned $5 thousand in royalty revenues on net sales under the Solasia License and Collaboration Agreement.

Critical Accounting Policies and Significant Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations is based upon our financial statements, which have been prepared in accordance with generally accepted accounting principles or GAAP. 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.

Revenue Recognition from Collaboration Agreements

We primarily generate revenue through collaboration arrangements with strategic partners for the development and commercialization of product candidates. Commencing January 1, 2018, we recognized revenue in accordance with Financial Accounting Standards Board ("FASB") ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). 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.

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.

Income Taxes

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

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 Policies* included in this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is contained on pages F-1 through F-24 of this Annual Report and is incorporated herein by reference. All share numbers and share prices presented in this Item 8 have been adjusted to reflect the 1-for-15 reverse stock split of the Company's common stock effected on January 31, 2024 and the 1-for-10 reverse stock split of the Company's common stock effected on July 17, 2024.

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

On June 19, 2024, we dismissed RSM US LLP ("RSM") as its independent registered public accounting firm. The decision to dismiss RSM was approved by the Company's Audit Committee. The change in our independent registered public accounting firm is not the result of any disagreement with RSM.

The reports of RSM on the Company's financial statements for the fiscal years ended December 31, 2023 and 2022, did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles, except that the reports for the fiscal years ended December 31, 2023 and 2022 included an explanatory paragraph indicating that there was substantial doubt about the Company's ability to continue as a going concern.

On June 19, 2024, following approval by the Audit Committee, we engaged Cherry Bekaert LLP as our new independent registered public accounting firm to succeed RSM.

Neither the Company nor anyone on behalf of the Company has consulted with Cherry Bekaert LLP during the Company's fiscal years ended December 31, 2023 and 2022, and in the subsequent interim period through June 19, 2024, regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that Cherry Bekaert LLP concluded was an important factor considered by the Company in reaching a decision as to an accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a "disagreement" (as defined in Item 304(a)(1)(iv) of Regulation S-K) or a "reportable event" (as described in Item 304(a)(1)(v) of Regulation S-K).

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer and our principal accounting officer, we have evaluated the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) or 15d-15(e) promulgated under the Exchange Act, as of December 31, 2024. Based on that evaluation, our principal executive officer and principal financial officer has concluded that as of December 31, 2024, our disclosure controls and procedures were not effective.

We note that the design of any system of controls 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 the stated goals under all potential future conditions.

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

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

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer and our principal accounting officer, we assessed our internal control over financial reporting as of December 31, 2024, 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 determined that our internal controls over our financial reporting was not effective due to the lack of sufficient number of personal to allow for the required segregation of duties as of December 31, 2024, based on the criteria discussed above.

Inherent Limitations on Internal Controls

Our management do not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute

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

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) of the Exchange Act) that occurred during the year ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Trading Plans

During the year ended December 31, 2024, no director or Section 16 officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

Policy Prohibiting Insider Trading and Related Procedures.

Our insider trading policy has been reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and Nasdaq listing standards. Our Insider Trading Policy is filed hereto as Exhibit 19.1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2025 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(1) Financial Statements:

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

(2) Financial Statement Schedules:

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

(3) Exhibits:

Exhibit No.	Description of Document
2.1	Agreement and Plan of Merger among the Registrant (formerly "EasyWeb, Inc."), ZIO Acquisition Corp. and ZIOPHARM, Inc., dated August 3, 2005 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K, SEC File No. 000-32353, filed August 9, 2005).
3.1	Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed July 17, 2024)
3.2	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).
3.3	Amended and Restated Bylaws of the Registrant, dated as of September 21, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed September 22, 2020).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form SB-2, SEC File No. 333-129020, filed October 14, 2005).
4.2	Form of Option for the Purchase of Shares of common stock dated August 30, 2004 and issued to The University of Texas M. D. Anderson Cancer Center (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-KSB, SEC File No. 000-32353, filed March 20, 2006).
4.3	Schedule identifying Material Terms of Options for the Purchase of Shares of Common Stock (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-KSB, SEC File No. 000-32353, filed March 20, 2006).
4.4	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed November 13, 2018).
4.5#	Warrant to Purchase Common Stock issued to The University of Texas M. D. Anderson Cancer Center (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 2, 2020).
4.6	Form of Warrant to Purchase Shares of Common Stock issued to SVB and certain of its Affiliates, dated December 28, 2021 (incorporated by reference to Exhibit 4.6 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
4.7	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.2+	Employment Agreement, dated as of January 21, 2024, by and between the Registrant and Dale Curtis Hogue (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed May 15, 2024.
10.3+	ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed September 24, 2018).
10.4+	Form of Restricted Stock Agreement Granted Under the ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed June 26, 2012).
10.5+	Form of Option Agreement Granted Under the ZIOPHARM Oncology, Inc. 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed June 26, 2012).

10.7+	Form of Inducement Award Grant Notice and Inducement Award Grant Agreement (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8, SEC File No. 333-238090, filed May 8, 2020).
10.8+	ZIOPHARM Oncology, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K SEC File No. 001-33038 filed July 1, 2020).
10.9+	Form of Restricted Stock Agreement Granted Under the ZIOPHARM Oncology, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.10+	Form of Stock Option Agreement Granted Under the ZIOPHARM Oncology, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.11+	Form of Indemnity Agreement for directors and executive officers (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed January 31, 2013).
10.16+	Employment Agreement, dated August 24, 2021, by and between the Registrant and Kevin S. Boyle Sr. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed August 30, 2021).
10.23#	Form of Retention Bonus Agreement (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 1, 2021).
10.24#	License Agreement by and among the Registrant, Intrexon Corporation and The University of Texas System Board of Regents on behalf of The University of Texas M.D. Anderson Cancer Center dated as of January 13, 2015 (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed January 28, 2015).
10.25†	Exclusive License Agreement by and between the Registrant, Precigen, Inc. and Intrexon Corporation, dated October 5, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed November 9, 2018).
10.26#	Amendment No. 1 to the Exclusive License Agreement by and between the Registrant and PGEN Therapeutics, Inc. (formerly known as Precigen, Inc.), dated October 15, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q SEC File No. 001-33038, filed November 5, 2020).
10.27	Amended and Restated Exclusive License Agreement, dated, April 3, 2023, by and between the Registrant and Precigen, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q SEC File No. 001-33038, filed May 10, 2023).
10.28†	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).
10.29#	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).
10.30	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).
10.31	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).
10.32	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).
10.33	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).
10.34#	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).
10.35#	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).
10.36#	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).
10.37#	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).

10.38#	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).
10.39#	Third Amendment to Patent License Agreement, dated as of April 16, 2021, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.40#	Fourth Amendment to Patent License Agreement, dated as of May 4, 2021, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.41#	Fifth Amendment to Patent License Agreement, dated as of August 13, 2021, by and between the Registrant and the National Cancer Institute (incorporated by reference to Exhibit 10.40 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.42#	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).
10.43	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).
10.44#	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).
10.45	Third Amendment to the Cooperative Research and Development Agreement, dated March 15, 2022, by and among the National Cancer Institute and the Registrant (incorporated by reference to Exhibit 10.44 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.46	Fourth Amendment to the Cooperative Research and Development Agreement, dated June 24, 2022, by and between the National Cancer Institute and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed August 15, 2022).
10.47	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).
10.48	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).
10.49	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).
10.50	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).
10.51	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).
10.52	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).
10.53	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).
10.54	First Amendment to the Loan and Security Agreement by and among the Registrant, the lenders party thereto and Silicon Valley Bank, as administrative agent and collateral agent, dated December 28, 2021 (incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed March 30, 2022).
10.55	Equity Distribution Agreement, dated August 12, 2022, by and between Piper Sandler & Co. and the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed August 15, 2022).

10.56	Underwriting Agreement, dated as of November 29, 2022, by and between Cantor Fitzgerald & Co. and the Registrant (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed November 30, 2022).
10.57+	Retention Agreement, dated as of August 14, 2023, between the Registrant and Melinda Lackey (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed November 14, 2023).
10.58+	Retention Agreement, dated as of August 14, 2023, between the Registrant and Drew Deniger (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, SEC File No. 001-33038, filed November 14, 2023).
10.59+	Consulting Agreement, dated as of November 14, 2023, between the Registrant and Melinda Lackey (incorporated by reference to Exhibit 10.59 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed April 1, 2024).
10.60+	Separation Agreement, dated as of December 22, 2023, between the Registrant and Kevin S. Boyle, Sr. (incorporated by reference to Exhibit 10.59 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed April 1, 2024).
10.61+	Consulting Agreement, dated as of December 22, 2023, between the Registrant and Kevin S. Boyle, Sr. (incorporated by reference to Exhibit 10.59 to the Registrant's Annual Report on Form 10-K, SEC File No. 001-33038, filed April 1, 2024).
10.62+*	Consulting Agreement, dated as of February 21, 2024, between the Registrant and Ferdinand Groenewald.
23.1*	Consent of Independent Registered Public Accounting Firm.
19.1*	Insider Trading Policy
23.2*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer and Principal Financial 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.
97.1*	Alaunos Therapeutics, Inc. Clawback Policy.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page Interactive Data File-the cover page interactive data is embedded within the Inline XBRL document or included within the Exhibit 101 attachments

*	Filed herewith.
**	Furnished herewith.
+	Indicates management contract or compensatory plan.
†	Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions of this document.
#	Portions of this document (indicated by "[***]") have been omitted because such information is not material and is the type of information that the Registrant treats as private or confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ALAUNOS THERAPEUTICS, INC.

Date: March 31, 2025

By: /s/ Dale Curtis Hogue, Jr.
Dale Curtis Hogue, Jr.
Interim Chief Executive Officer and Director
(Principal Executive Officer and Principal Financial Officer)

Date: March 31, 2025

By: /s/ Ferdinand Groenewald
Ferdinand Groenewald
Vice President, Finance
(Principal Accounting Officer)

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/ Dale Curtis Hogue, Jr. Dale Curtis Hogue, Jr.	Interim Chief Executive Officer and Director *(Principal Executive Officer and Principal Financial Officer)*	March 31, 2025
/s/ Ferdinand Groenewald Ferdinand Groenewald	Vice President, Finance *(Principal Accounting Officer)*	March 31, 2025
/s/ Robert Hofmeister Robert Hofmeister	Director	March 31, 2025
/s/ Robert W. Postma Robert W. Postma	Director	March 31, 2025
/s/ Jaime Vieser Jaime Vieser	Director	March 31, 2025
/s/ Holger Weis Holger Weis	Director	March 31, 2025

Alaunos Therapeutics, Inc.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Alaunos Therapeutics, Inc. (the "Company") as of December 31, 2024, and the related statements of operations, stockholders' equity, and cash flows the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

The financial statements of the Company as of and for the year ended December 31, 2023, before the retroactive adjustments described in Note 3 with respect to the July 2024 one-for-ten reverse stock split were audited by other auditors whose report, dated April 1, 2024, expressed an unqualified opinion, with an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern, on those statements. We also audited the adjustments described in Note 3 that were applied retroactively to the 2023 financial statements to reflect the July 2024 one-for-ten reverse stock split and the related disclosures included therein. In our opinion, such adjustments and related disclosures are appropriate and have been properly applied. We were not engaged to audit, review, or apply any procedures to the 2023 financial statements of the Company other than with respect to the adjustments and disclosures referred to herein and, accordingly, we do not express an opinion or any other form of assurance on the 2023 financial statements taken as a whole.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's evaluations of the events and conditions and management's plans regarding those matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters 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. We determined that there were no critical audit matters.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2024.

Tampa, Florida
March 31, 2025

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, before the effects of the adjustments to retrospectively apply the reverse stock split effective July 17, 2024 described in Note 3, the accompanying balance sheet of Alaunos Therapeutics, Inc. (the Company) as of December 31, 2023, the related statements of operations, changes in stockholders' equity and cash flows for the year then ended, and the related notes to the financial statements (collectively, the financial statements). The 2023 financial statements before the effects of the adjustments around the July 17, 2024 reverse stock split described in Note 3 are not presented herein. In our opinion, before the effects of the adjustments to retrospectively apply the reverse stock split effective July 17, 2024, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to retrospectively apply the changes in the Company's disclosures related to the reverse stock split effective July 17, 2024 described in Note 3 and, accordingly we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by other auditors.

The Company's Ability to Continue as a Going Concern

The accompanying 2023 financial statements were prepared assuming that the Company would continue as a going concern. As discussed in Note 1 to the 2023 financial statements, the Company had suffered recurring losses from operations since inception and would be required to raise additional capital to fund operations. This raised substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters were also described in Note 1 to the 2023 financial statements. The 2023 financial statements did not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ RSM US LLP

We served as the Company's auditor from 2010 to 2024.

Boston, Massachusetts
April 1, 2024

Alaunos Therapeutics, Inc.

BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2024	December 31, 2023
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 1,091	$ 6,062
Receivables	5	1
Prepaid expenses and other current assets	1,659	2,198
Total current assets	2,755	8,261
Property and equipment, net	—	2
Total assets	$ 2,755	$ 8,263
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 516	$ 616
Accrued expenses	176	1,340
Total current liabilities	692	1,956
Total liabilities	$ 692	$ 1,956
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock $0.001 par value; 5,000,000 shares authorized, 1,601,252 shares issued and outstanding at December 31, 2024 and at December 31, 2023	2	2
Additional paid-in capital	922,507	922,072
Accumulated deficit	(920,446)	(915,767)
Total stockholders' equity	2,063	6,307
Total liabilities and stockholders' equity	$ 2,755	$ 8,263

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,	
	2024	**2023**
Revenue	$ 10	$ 5
Operating expenses:		
Research and development	362	16,279
General and administrative	4,460	12,219
Gain on lease modification	—	(298)
Restructuring costs	—	1,269
Property and equipment and right-of-use asset impairment	—	4,803
Total operating expenses	4,822	34,272
Loss from operations	(4,812)	(34,267)
Other income (expense):		
Interest expense	—	(1,921)
Other income, net	133	1,048
Other income (expense), net	133	(873)
Net loss	$ (4,679)	$ (35,140)
Basic and diluted net loss per share	$ (2.92)	$ (21.97)
Weighted average common shares outstanding, basic and diluted	1,601,252	1,599,532

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

Alaunos Therapeutics, Inc.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(in thousands, except share and per share data)

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2023	1,602,738	$ 2	$ 919,180	$ (880,627)	$ 38,555
Stock-based compensation	—	—	2,800	—	2,800
Issuance of common stock, net of expenses	1,442	—	92	—	92
Cancelled restricted common stock	(2,928)	—	—	—	—
Net loss	—	—	—	(35,140)	(35,140)
Balance at December 31, 2023	1,601,252	$ 2	$ 922,072	$ (915,767)	$ 6,307
Stock-based compensation	—	—	435	—	435
Net loss	—	—	—	(4,679)	(4,679)
Balance at December 31, 2024	1,601,252	2	922,507	(920,446)	2,063

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

Alaunos Therapeutics, Inc.

STATEMENTS OF CASH FLOWS

(in thousands)

	For the Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (4,679)	$ (35,140)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2	2,315
Property and equipment right-of-use asset impairment	—	4,803
Amortization of financing costs	—	1,339
Stock-based compensation	435	2,800
Decrease in the carrying amount of right-of-use assets	—	286
Gain on lease modification and termination	—	(298)
Loss on sale of equipment, net	—	7
Changes in operating assets and liabilities:		
Receivables	(4)	3
Prepaid expenses and other current assets	539	(1,399)
Deposits	—	42
Other non-current liability	—	500
Accounts payable	(100)	(773)
Accrued expenses	(1,164)	(3,989)
Lease liabilities	—	(610)
Other liabilities, non-current	—	(28)
Net cash used in operating activities	(4,971)	(30,142)
Cash flows from investing activities:		
Purchases of property and equipment	—	(197)
Proceeds from the disposal of property and equipment	—	1,543
Net cash provided by investing activities	—	1,346
Cash flows from financing activities:		
Proceeds from the issuance of common stock	—	92
Repayment of long-term debt	—	(18,105)
Debt extinguishment	—	(125)
Net cash used in financing activities	—	(18,138)
Net decrease in cash, cash equivalents and restricted cash	(4,971)	(46,934)
Cash, cash equivalents and restricted cash, beginning of period	6,062	52,996
Cash and cash equivalents, end of period	$ 1,091	$ 6,062
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ —	$ 2,063
Reduction in right-of-use assets for modification and termination	$ —	$ 1,839

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 pre-clinical obesity and metabolic disorder and clinical-stage oncology-focused cell therapy company with a current focus on developing small molecules that are expected to be efficacious against obesity and other metabolic disorders and was historically involved in the development of adoptive TCR therapies, designed to treat multiple solid tumor types in large cancer patient populations with unmet clinical needs. The Company is currently working to develop novel small molecule-based obesity therapeutics. See Note 11 - Restructuring regarding a strategic reprioritization of the Company's business.

The Company's operations to date have consisted primarily of conducting research and development and raising capital to fund those efforts.

As of December 31, 2024 there were 1,601,252 shares of common stock outstanding and an additional 142,745 shares of common stock reserved for issuance pursuant to outstanding stock options and warrants.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business.

The Company 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, 2024, the Company had approximately $1.1 million of cash and cash equivalents. The Company's accumulated deficit at December 31, 2024 was approximately $920.4 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 2025. The Company continues to explore strategic alternatives, including, but not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions. The Company's ability to continue operations after its current cash resources are exhausted depends on future events, including its ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given, nor are within the Company's control. If adequate additional funds are not available when required, or if the Company is unsuccessful in entering into partnership agreements for further development of its product candidates, management may need to curtail its development efforts and planned operations to conserve cash until sufficient additional capital is raised. There can be no assurances that such a plan would be successful.

Based on the current cash forecast and the Company's dependence on its ability to obtain additional financing to fund its operations after the current resources are exhausted, about which there can be no certainty, management has determined that the Company's present capital resources will not be sufficient to fund its planned operations for at least one year from the issuance date of the financial statements, and substantial doubt as to the Company's ability to continue as a going concern exists.

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

2. Financings

2021 Loan and Security Agreement

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

Effective December 28, 2021, the Company, entered into an amendment to the Loan and Security Agreement, or the First Amendment. The First Amendment extended the interest-only period through August 31, 2022. The First Amendment also eliminated the Term B Tranche, which remained unfunded, leaving only the Term A Tranche, or the SVB Facility. Under the amended Loan and Security Agreement, the SVB Facility was to mature on August 1, 2023. On May 1, 2023, the Company repaid its outstanding debt obligations under the amended Loan and Security Agreement in their entirety.

2022 Public Offering

On November 29, 2022, the Company entered into an underwriting agreement, or the Underwriting Agreement, with Cantor as the sole underwriter, relating to the issuance and sale in an underwritten offering, or the Offering, of 161,524 shares, or the Firm Shares, of the Company's common stock to Cantor at a price of $18.573 per share.

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

Under the terms of the Underwriting Agreement, the Company granted Cantor an option, exercisable for 30 days, to purchase up to an additional 24,228 shares of common stock, which we refer to, together with the Firm Shares, as the Shares, at the same price per share as the Firm Shares. On January 5, 2023, Cantor partially exercised its option to purchase an additional 1,442 shares of common stock.

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.

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

Cash and Cash Equivalents

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

Concentrations of Credit Risk

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

Property and Equipment

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

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

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

Long-Lived Assets

Assessments of long-lived assets and the remaining useful lives of such long-lived assets are reviewed for impairment whenever a triggering event occurs or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An asset, or group of assets, is considered to be impaired when the undiscounted estimated net cash flows expected to be generated by the asset, or group of assets, are less than its carrying amount. The impairment recognized is the amount by which the carrying amount exceeds the fair market value of the impaired asset, or group of assets, based on the present value of the expected future cash flows associated with the use of the asset. During the year ended December 31, 2023, the Company recorded impairment charge of $4.8 million, which was primarily related to leasehold improvements of $3.8 million and lab equipment of $1.0 million.

Operating Segments

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the Company's chief operating decision maker ("CODM") and relied upon when making decisions regarding resource allocation and assessing performance. When evaluating the Company's financial performance, the CODM reviews total revenues, total expenses, and expenses by functional classification; using this information to make decisions on a company-wide basis. The Company views its operations and manages its business in one operating segment.

Warrants

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

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

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, 2024 and 2023 are as follows:

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	**Balance as of December 31, 2024**	**Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Cash equivalents	$ 779	$ 779	$ —	$ —

($ in thousands)		Fair Value Measurements at Reporting Date Using		
Description	**Balance as of December 31, 2023**	**Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Cash equivalents	$ 5,744	$ 5,744	$ —	$ —

The cash equivalents represent demand deposit accounts and deposits in a short-term United States treasury money market mutual fund quoted in an active market and classified as a Level 1 asset. There have been no changes to the valuation methods during the years ended December 31, 2024 and 2023. The Company had no financial assets or liabilities that were classified as Level 2 or Level 3 during the years ended December 31, 2024 and 2023.

Revenue Recognition from Collaboration Agreements

Revenue for the year ended December 31, 2024 consisted of $10 thousand and for the year ended December 31, 2023 consisted of $5 thousand. For the years ended December 31, 2024 and 2023, the Company recognized revenue through its Collaboration Agreement with Solasia Pharma K.K. primarily due to the achievement of milestones, as further described in Note 9, *Commitments and Contingencies.*

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 and third-party vendors 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.

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

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

Income Taxes

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

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

Accounting for Stock-Based Compensation

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

The Company recognized the full impact of its share-based employee payment plans in the statements of operations for each of the years ended December 31, 2024 and 2023 and did not capitalize any such costs on the balance sheets. The Company recognized $0.4 million of compensation expense related to stock options for the year ended December 31, 2024 and $2.5 million of compensation expense related to stock options for the year ended December 31, 2023. The Company recognized $0.0 million of compensation expense related to restricted stock for the year ended December 31, 2024 and $0.3 million for the year ended December 31, 2023 (refer to Note 13, *Stock Option Plan*). The total compensation expense relating to vesting of stock options and restricted stock awards for the year ended December 31, 2024 was $0.4 million and $2.8 million for the year ended December 31, 2023.

The following table presents share-based compensation expense included in the Company’s statements of operations:

(in thousands)	For the Year Ended December 31, 2024	2023
Research and development	$ 17	$ 439
General and administrative	418	2,361
Stock-based compensation expense	$ 435	$ 2,800

The fair value of each stock option is estimated at the date of grant using the Black-Scholes option pricing model. 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 historical experience. The Company calculated expected term using the simplified method described in SEC Staff Accounting Bulletin, or SAB, No. 107 and No. 110.

Reverse Stock Splits

Alaunos Therapeutics, Inc.

NOTES TO FINANCIAL STATEMENTS

On January 31, 2024, the Company filed a Second Amended and Restated Certificate of Incorporation (the "Charter Amendment") with the Secretary of State of the State of Delaware in order to effect a reverse stock split of the Company's common stock at a ratio of 1-for-15 (the "Reverse Split"). The Charter Amendment decreased the number of authorized shares of common stock from 520,000,000 to 34,666,667. The Charter Amendment does not affect the par value of the Company's common stock or change the number of authorized shares or par value of the Company's preferred stock. The Charter Amendment became effective on January 31, 2024.

On July 17, 2024, the Company filed a Third Amended and Restated Certificate of Incorporation or Third Charter Amendment with the Secretary of State of the State of Delaware in order to effect a reverse stock split of the Company's common stock at a ratio of 1-for-10 (the "Second reverse Split", the "Reverse Splits") or the Second Reverse Split, collectively the Reverse Splits. The Third Charter Amendment decreased the number of authorized shares of common stock from 34,666,667 to 5,000,000. The Third Charter Amendment does not affect the par value of the Company's common stock or change the number of authorized shares or par value of the Company's preferred stock. The Third Charter Amendment became effective on July 17, 2024.

No fractional shares were issued in connection with the Reverse Splits. Stockholders of record who would otherwise have been entitled to receive fractional shares as a result of the Reverse Splits received a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing sales price per share of the common stock (as adjusted for the Reverse Splits) on the Nasdaq Capital Market on January 31, 2024 and July 17, 2024.

All share and per share amounts of common stock, options, warrants, and restricted stock in the accompanying financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the Reverse Splits as if they had occurred at the beginning of the earliest period presented.

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.

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, 2024 and 2023 as the result would be antidilutive. Such potential common shares on December 31, 2024 and 2023 consist of the following:

	December 31,	
	2024	2023
Common stock options	33,237	46,589
Warrants	26,555	145,239
	59,792	191,828

New Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, "Improvements to Reportable Segment Disclosures (Topic 280)" which is intended to improve reportable segment disclosure requirements, primarily through incremental disclosures of segment information on an annual and interim basis for all public entities. The ASU expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items and interim disclosures of a reportable segment's profit or loss and assets. The ASU is effective for our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, and interim periods thereafter with and before it has been applied retrospectively to all prior periods presented.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide for enhanced income tax

information primarily through changes to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for the Company prospectively to all annual periods beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of this standard.

4. Debt

On August 6, 2021, the Company entered into the Loan and Security Agreement with SVB. The Loan and Security Agreement provided for the funding of the Term A Tranche at the closing, with the Term B Tranche available if certain funding and clinical milestones were met by August 31, 2022. The SVB Facility and related obligations under the Loan and Security Agreement were secured by substantially all of the Company's properties, rights and assets, except for its intellectual property (which was subject to a negative pledge under the Loan and Security Agreement). In addition, the Loan and Security Agreement contained customary representations, warranties, events of default and covenants.

On December 28, 2021, the Company entered into the First Amendment to the Loan and Security Agreement. The First Amendment eliminated the unfunded Term B Tranche, among other things. The SVB Facility bore 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%.

All outstanding obligations under the amended Loan and Security Agreement were due and payable on August 1, 2023. In connection with the payment of all of the Company's outstanding obligations, the Company also owed SVB 5.75% of the original principal amounts borrowed as a final payment, or the Final Payment. Effective March 30, 2023, the Company entered into a Third Amendment to the Loan and Security Agreement, or the Third Amendment. Under the terms of the Third Amendment, the Company was no longer required to maintain all of its operating accounts, depository accounts and excess cash with SVB or one of its affiliates, and was instead only required to maintain a single operating or depository account at Silicon Valley Bank. The Third Amendment also modified the cash collateralization requirement, such that the Company was required to cash collateralize the entire sum of the outstanding principal amount of the SVB Facility, plus an amount equal to the Final Payment, which amount was to be reduced commensurate with each regularly scheduled monthly payment of principal and interest on the SVB Facility.

On May 1, 2023, the Company paid SVB an amount equal to the entire outstanding principal amount under the SVB Facility, all accrued and unpaid interest and the Final Payment. In accordance with the First Amendment, the payment was subject to a prepayment premium of 2.00%. During the year ended December 31, 2023, the Company recorded the remaining amounts associated with the Final Payment of $0.5 million and the prepayment premium of $0.1 million as interest expense within the statement of operations.

In connection with its entry into the Loan and Security Agreement in August 2021, the Company issued to SVB warrants to purchase (i) up to 2,886 shares of the Company’s common stock, in the aggregate, and (ii) up to an additional 2,886 shares of common stock, in the aggregate, in the event the Company achieved certain clinical milestones, in each case at an exercise price per share of $333.

In connection with its entry into the First Amendment in December 2021, the Company amended and restated the warrants issued to SVB. As amended and restated, the warrants are for up to 4,331 shares of the Company's common stock, in the aggregate, with an exercise price of $174 per share, or the SVB Warrants. The SVB Warrants expire on August 6, 2031.

The issuance costs for the Loan and Security Agreement, including the First Amendment, were approximately $1.2 million and primarily related to the SVB Warrants, which were amortized into interest expense over the term of the loan. Interest expense, including the amortization of issuance costs, was $1.9 million for the year ended December 31, 2023.

As a result of the repayments there were no debt obligations outstanding at December 31, 2024 or 2023.

5. Property and Equipment, net

Property and equipment, net, consists of the following:

($ in thousands)	December 31, 2024	December 31, 2023
Office and computer equipment	$ 15	$ 15
	15	15
Less: accumulated depreciation	(15)	(13)
Property and equipment, net	$ -	$ 2

Depreciation expense for the year ended December 31, 2024 was $2.0 thousand and was $2.3 million for the year ended December 31, 2023.

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6. Accrued Expenses

Accrued expenses consist of the following:

($ in thousands)	2024	2023
Clinical	$ 97	$ 568
Employee compensation	-	43
Professional services	79	717
Manufacturing services	-	12
	$ 176	$ 1,340

7. Related Party Transactions

Joint Venture with TriArm Therapeutics/Eden BioCell

On December 18, 2018, the Company and TriArm Therapeutics, Ltd., or TriArm, launched Eden BioCell, Ltd., or Eden BioCell, as a joint venture to lead commercialization of the Company's *Sleeping Beauty*-generated CAR-T therapies in the People's Republic of China (including Macau and Hong Kong), Taiwan and Korea. The Company licensed to Eden BioCell the rights in Greater China for its third-generation Sleeping Beauty-generated CAR-T therapies targeting the CD19 antigen. Eden BioCell is owned equally by the Company and TriArm and the parties share decision-making authority. TriArm contributed $10.0 million to Eden BioCell and has committed up to an additional $25.0 million to this joint venture. TriArm also managed all clinical development in the territory pursuant to a master services agreement between TriArm and Eden BioCell. James Huang was the founder and serves as managing partner of Panacea Venture, which is an investor in TriArm. Mr. Huang was the Chair of the Company's board of directors until September 22, 2023 and had been a director since July 2020. He also serves as a member of Eden BioCell's board of directors.

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

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

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

In September 2021, TriArm and the Company mutually agreed to dissolve the joint venture, which has now been terminated. The Eden BioCell entity has been dissolved as of July 2023.

Collaboration with Dune Lake Capital

In January 2023, the Company entered into a consulting agreement with Dune Lake Capital, LLC, or Dune Lake Capital, which was founded by Dale Curtis Hogue, Jr., the Company's interim Chief Executive Officer. During the year ended December 31, 2023, the Company recorded expenses of approximately $37 thousand for consulting services performed by Dune Lake Capital with respect to the period from January 2023 to August 2023. The Company did not incur expenses to Dune Lake Capital during the year ended December 31, 2024.

On January 20, 2024, the Board of Directors appointed Dale Curtis Hogue, Jr. as Interim Chief Executive Officer of the Company, effective immediately. On January 21, 2024, the Company entered into an employment agreement with Mr. Hogue, under which he will receive an annual base salary of $250 thousand. Mr. Hogue was awarded 40,000 shares of common stock of the Company with an exercise price of $1.80.

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8. Leases

In April 2022, the Company modified its real estate lease agreement executed on December 15, 2020 with MD Anderson for office space in Houston, Texas, which reduced the Company's leased space from 18,111 square feet to 3,228 square feet. As a result, the associated lease liability and right-of-use asset were remeasured to $0.4 million based on revised lease payments. A gain of $0.1 million was recorded on the lease modification during the year ended December 31, 2022.

In June 2022, the Company executed an agreement to sub-sublease 4,772 square feet of subleased office space in Boston. For the year ended December 31, 2023, the Company recognized $43 thousand in lease income. Lease income is classified within other income on the statement of operations.

On April 19, 2023, the Company terminated its office lease in Boston, Massachusetts, which was set to expire on August 31, 2026. In connection with the termination, the Company also assigned to the landlord its sub-sublease of the Boston office space, which had a term expiring on June 30, 2025 with an option to extend through July 31, 2026. Termination costs for the Boston office lease were $0.2 million. A gain of $0.2 million was recorded on the lease termination during the year ended December 31, 2023.

In August 2023, in accordance with the lease agreement, the Company notified, as landlord, of its intention to terminate. As a result, the associated lease liability and right-of-use asset were remeasured to $19 thousand, reflecting the revised lease payments and term end date of November 2023.

On November 1, 2023, the Company and MD Anderson, as landlord, agreed to mutually terminate the leases dated October 15, 2019 and April 7, 2020, which represented office space totaling 14,037 square feet, effective November 15, 2023. As a result, the Company agreed to make a final payment of $0.1 million to the landlord. A gain of $0.1 million was recorded on the lease termination during the year ended December 31, 2023.

The components of lease expense were as follows:

($ in thousands)	Year Ended December 31, 2024	Year Ended December 31, 2023
Operating lease cost	$ —	$ 428
Total lease cost	$ —	$ 428
Weighted-average remaining lease term (years)	—	—
Weighted-average discount rate	—	—

The Company paid $0.4 million in operating lease costs for the year-ended December 31, 2023. The Company did not recognize new operating lease assets obtained in exchange for operating lease liabilities for the year-ended December 31, 2023. The Company did not have any leases, other than a short-term lease, as of December 31, 2023.

9. Commitments and Contingencies

Exclusive License Agreement with Precigen

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. Except where the context otherwise requires, the Company refers to PGEN and Precigen together as Precigen. Pursuant to the terms of the License Agreement, the Company had exclusive, worldwide rights to research, develop and commercialize (i) TCR products designed for neoantigens for the treatment of cancer, (ii) products utilizing Precigen's RheoSwitch® gene switch, or RTS, for the treatment of cancer, referred to as IL-12 Products and (iii) CAR products directed to (A) CD19 for the treatment of cancer, referred to as CD19 Products, and (B) BCMA for the treatment of cancer, subject to certain obligations to pursue such target under the License and Collaboration Agreement effective March 27, 2015 between the Company, Precigen and ARES TRADING S.A., a subsidiary of Merck KGaA, as assigned by Precigen to PGEN. Under the License Agreement, the Company also had 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 was responsible for all aspects of the research, development and commercialization and was required to use commercially reasonable efforts to develop certain products.

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In consideration of the licenses and other rights granted by Precigen, the Company was required to pay Precigen an annual license fee of $0.1 million, reimburse Precigen for certain historical costs, pay Precigen milestones up to an additional $52.5 million for each exclusively licensed program upon the achievement of certain milestones, and pay Precigen tiered royalties up to a maximum royalty amount of $100.0 million in the aggregate. The Company was also obligated to pay Precigen 20% of any sublicensing income received by us relating to the licensed products. The Company was responsible for all development costs associated with each of the licensed products.

On April 3, 2023, the Company entered into the Amended and Restated Exclusive License Agreement with Precigen, or the A&R License Agreement, which restated and amended the parties' previous license agreement in full. Under the A&R License Agreement, the Company still had exclusive, worldwide rights to research, develop and commercialize TCR products designed for neoantigens or driver mutations for the treatment of cancer and non-exclusive rights to use non-driver mutation TCRs. On October 4, 2024, pursuant to Section 10.2 of the License Agreement, the Company duly notified Precigen of its full termination of all rights under the License Agreement.

The Company remains solely responsible for all aspects of the research, development and commercialization of the exclusively licensed products for the treatment of cancer. The (i) products utilizing Precigen’s RheoSwitch® gene switch, or RTS, for the treatment of cancer, referred to as IL-12 Products and (ii) CAR products directed to (A) CD19 for the treatment of cancer, referred to as CD19 Products, and (B) BCMA for the treatment of cancer, subject to certain obligations to pursue such target under the License and Collaboration Agreement effective March 27, 2015 between the Company, Precigen and ARES TRADING S.A., a subsidiary of Merck KGaA, as assigned by Precigen to PGEN are no longer exclusively licensed to the Company. The Company is no longer obligated to use commercially reasonable efforts for the exclusively licensed products. The A&R License Agreement further eliminates any royalty or milestone obligations to Precigen, with an annual license fee of $75 thousand due on the anniversary of the A&R License Agreement effective date. Precigen is no longer obligated to pay the Company royalties on the net sales derived from the sale of Precigen's CAR 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 a license agreement, or the MD Anderson License with MD Anderson (which Precigen subsequently assigned to PGEN). Pursuant to the MD Anderson License, the Company, together with Precigen, 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.

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.

As provided under the MD Anderson License, the Company provided funding for research and development activities in support of the research programs under the 2015 R&D Agreement for a period of three years and in an amount of no less than $15.0 million and no greater than $20.0 million per year. On November 14, 2017, the Company entered into an amendment to the 2015 R&D Agreement, extending its term until April 15, 2021. In connection with the execution of the 2019 R&D Agreement described below, on October 22, 2019, the Company amended the 2015 R&D Agreement to extend the term of the 2015 R&D Agreement until December 31, 2026 and to allow cash resources on hand at MD Anderson under the 2015 R&D Agreement to be used for development costs under the 2019 Research and Development Agreement, or the 2019 R&D Agreement, which the Company entered into on October 22, 2019, with MD Anderson, pursuant to which the Company agreed to collaborate with respect to the TCR program. For the year ended December 31, 2023 the Company incurred clinical expenses of $0.1 million from MD Anderson related to the 2015 R&D Agreement. The Company did not incur clinical costs from MD Anderson related to the 2015 R&D Agreement for the year ended December 31, 2024.

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

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

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

intellectual property to develop and commercialize autologous TCR products manufactured using viral gene transfer technologies and any products outside the field of oncology and a non-exclusive license for allogenic TCR products manufactured using viral-based technologies.

Under the 2019 R&D Agreement, the Company agreed, beginning on January 1, 2021, to reimburse MD Anderson up to a total of $20.0 million for development costs under the 2019 R&D Agreement, after the funds from the 2015 R&D Agreement are exhausted. In addition, the Company will pay MD Anderson royalties on net sales of its TCR products. The Company is required to make performance-based payments upon the successful completion of clinical and regulatory benchmarks relating to its TCR products. The aggregate potential benchmark payments are $36.5 million, of which only $3.0 million will be due prior to the first marketing approval of the Company's TCR products. The royalty rates and benchmark payments owed to MD Anderson may be reduced upon the occurrence of certain events. The Company also agreed to sell its TCR products to MD Anderson at preferential prices and will sell the Company's TCR products in Texas exclusively to MD Anderson for a limited period of time following the first commercial sale of the Company's TCR products. For the year end December 31, 2024 the Company did not incur clinical expenses from MD Anderson related to the 2019 R&D Agreement, compared to the year ended December 31, 2023, the Company incurred clinical expenses of $0.8 million from MD Anderson related to the 2019 R&D 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, the Company issued MD Anderson a warrant to purchase 22,222 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 $0.15 per share, expires on December 31, 2026, and vests upon the occurrence of certain clinical milestones. As of December 31, 2024, the milestones have not been met.

License Agreement with the NCI

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

On October 27, 2023, the Company provided the NCI the requisite notice of its intent to terminate the Patent License, effective December 26, 2023. The Company discovered multiple proprietary TCRs targeting driver mutations through its hunTR TCR discovery platform, including many of the same *KRAS* and *TP53* mutations licensed from the NCI.

The Company incurred no expenses under this agreement in 2024, compared to $0.4 million in 2023.

Cooperative Research and Development Agreement (CRADA) with the NCI

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

The Company was responsible for providing the NCI with the test materials necessary for them to conduct their studies, and eventually, clinical trials pursuant to the CRADA. Inventions, data and materials discovered or produced in connection with performance of the research plan under the CRADA would have remained the sole property of the party who produced the discovery. The parties would have jointly owned all inventions jointly discovered under the research plan. The owner of any invention under the CRADA would have made the decision to file a patent covering the invention, or in the case of a jointly owned invention, the Company would have the first opportunity to file a patent covering the invention. If the Company failed to provide timely notice of its decision to the NCI or decided not to file a patent covering the joint invention, the NCI had the right to make the filing. For any invention solely owned by the NCI or jointly made by the NCI and the Company for which a patent application was filed, the U.S. Public Health service granted the Company an exclusive option to elect an exclusive or non-exclusive commercialization

license. For inventions owned solely by the NCI or jointly owned by the NCI and the Company, which were licensed according to the terms described above, the Company agreed to grant to the U.S. government a non-exclusive, non-transferable, irrevocable and paid up license to practice the invention or have the invention practiced on its behalf throughout the world. The Company was also required to grant the U.S. government a non-exclusive, non-transferable, irrevocable and paid up license to practice the invention or have the invention practiced on its behalf throughout the world for any of the Company's solely owned inventions. The agreement could be terminated by any of the parties upon 60 days' prior written consent.

On October 13, 2023, the Company terminated the CRADA per its terms.

The Company did not record expenses under the CRADA for the year ended December 31, 2024, compared to $0.5 million for year ended December 31, 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 milestones in varying amounts which, on a cumulative basis could total up to an additional $4.5 million. In addition, the Licensors are entitled to receive royalty payments on sales from a licensed product and will also be entitled to receive a portion of any fees that the Company may receive from a possible sublicense under certain circumstances. During the year ended December 31, 2024, the Company did not incur any milestone expenses or royalty expenses on sales under this agreement. During the year ended December 31, 2023, the Company did not incur any milestone expenses under this agreement, and the Company incurred $1 thousand in royalty expenses on sales under this agreement during the year ended December 31, 2023.

Collaboration Agreement with Solasia Pharma K.K.

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

As consideration for the license, the Company is eligible to receive from Solasia development- and sales-based milestones, a royalty on net sales of darinaparsin, once commercialized, and a percentage of any sublicense revenue generated by Solasia.

During the year ended December 31, 2024, the Company did not earn collaboration revenue and earned $10 thousand in royalty revenues on net sales under the Solasia License and Collaboration Agreement. During the year ended December 31, 2023, the Company did not earn collaboration revenue and earned $5 thousand in royalty revenues on net sales under the Solasia License and Collaboration Agreement.

KBI Biopharma Litigation

On March 17, 2023, KBI Biopharma, Inc., or KBI, filed a complaint against the Company in the District Court of Harris County, Texas, 165th Judicial District, asserting breach of an Amended and Restated Master Services Agreement between the Company and KBI relating to the development of an autologous gene modified T-cell therapy product, or the KBI Agreement. KBI was primarily seeking unspecified monetary damages in excess of $3.2 million. On May 1, 2023, the Company filed an answer generally denying all of KBI’s allegations and asserting affirmative and other defenses as well as counterclaims for breach of the KBI Agreement and conversion. On October 20, 2023, the Company entered into an agreement with KBI to settle all claims asserted by KBI against the Company and the Company's counterclaims against KBI at issue in the litigation for $1.0 million.

10. Warrants

The following is a summary of the Company's warrant activity for the years ended December 31, 2024:

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(in thousands, except share and per share data)	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Term (Years)
Outstanding, December 31, 2022	145,236	$ 863.25	2.17
Granted	-	-	
Exercised	-	-	
Forfeited	-	-	
Outstanding, December 31, 2023	145,236	$ 268.50	1.17
Granted	-	-	
Exercised	-	-	
Forfeited	(118,684)	1,050	
Outstanding, December 31, 2024	26,552	$ 28.50	2.75

11. Restructuring

On August 14, 2023, the Company announced a strategic reprioritization of its business and wind down of its TCR-T Library Phase 1/2 Trial. In connection with the reprioritization, the Company reduced its workforce during the third and fourth quarters of 2023. During the year ended December 31, 2023, the Company recorded termination benefits of $1.3 million, recorded in restructuring costs within the statement of operations. The termination benefits were fully paid as of December 31, 2023. During the year ended December 31, 2024, the Company did not incur any restructuring costs.

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, 2024 and 2023 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, 2024 and 2023 are as follows:

(in thousands)	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforwards	$ 154,634	$ 148,009
Start-up and pre-clinical studies	11,011	13,754
Research and development credit carryforwards	40,486	39,838
Stock-based compensation	699	681
Capitalized acquisition costs	1,050	1,570
Lease liability	—	—
Depreciation	1	1
Capitalized research expenses	5,400	7,176
Other	0	2
	213,281	211,031
Less valuation allowance	(213,281)	(211,031)
Total deferred tax assets	—	—
Right-of-use asset	—	—
Total deferred tax liabilities	$ —	$ —
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, 2024, the Company has aggregate net operating loss carryforwards for federal tax purposes of approximately $737 million, of which approximately $342 million expire at various dates through December 31, 2037 and approximately $395 million can be carried forward indefinitely. The Company is reducing its approximately $498 million

of state net operating loss carryforwards to $0 as these state net operating loss carryforwards all related to Massachusetts filings and, as of December 31, 2023 the Company no longer had any employees or property in Massachusetts and, as a result, the Company will no longer have income tax nexus in Massachusetts or an income tax filing obligation after the year ended December 31, 2023. Additionally, the Company has approximately $40.5 million of federal and state research and development credits at December 31, 2024, expiring in varying amounts through 2043, which may be available to reduce future taxes. The Company has reduced its Massachusetts credits carryforward to $0.

The Company has provided a valuation allowance for the full amount of its net deferred tax assets since it is more likely than not that these future benefits will not be realized. However, these deferred tax assets may be available to offset future income tax liabilities and expenses. The valuation allowance increased by $2,250 thousands in 2024 due primarily to the reduction of Massachusetts net operating loss carryforwards and Massachusetts 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)	**2024**	**2023**
Federal income tax at statutory rates	21%	21%
State income tax, net of federal tax benefit	(2)%	(92)%
Research and development credits	—%	2%
Research and development true-up	29%	(1)%
Stock-based compensation	0	—%
Federal/state rate change	0%	(3)%
Change in valuation allowance	(48)%	73%
Effective tax rate	—%	—%

The Company adopted ASC 740, *Accounting for Uncertain Tax Positions* on January 1, 2007. ASC 740 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes." ASC 740 prescribes a recognition threshold and measurement of a tax position taken or expected to be taken in a tax return. The Company did not establish any additional reserves for uncertain tax liabilities upon adoption of ASC 740. There were no adjustments to its uncertain tax positions in the years ended December 31, 2024 and 2023.

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

13. Stock Option Plan

The Company adopted the 2020 Equity Incentive Plan, or the 2020 Plan, in June 2020. As of December 31, 2024, there were 33,236 shares reserved for issuance and 142,745 shares available for future grant. The Company reserved 140,000 shares for issuance plus a carryover of 7,109 shares from the 2012 Plan for a total of 147,109 shares. In addition, returning shares from the 2012 Plan are available for issuance under the 2020 Plan.

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

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Stock option activity under the Company's stock options plans for the years ending December 31, 2024 and 2023 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, 2022	69,391	$ 276.00	8.69	$ 3
Granted	25,912	73.50		
Exercised	-	-		
Cancelled	(48,714)	177.00		
Outstanding, December 31, 2023	46,589	$ 268.50	7.64	$ —
Granted	13,289	10.84		
Exercised	-	-		
Cancelled	(26,641)	283.09		
Outstanding, December 31, 2024	33,237	$ 153.79	7.15	$ —
Options exercisable, December 31, 2024	23,903	$ 224.53	7.41	$ —
Options available for future grant, December 31, 2024	142,745			

The estimated weighted-average fair value of stock options granted to employees in the year ended December 31, 2024 was approximately $10.84 per share and was approximately $55.80 per share for the year ended December 31, 2023. On December 31, 2024, total unrecognized compensation costs related to non-vested stock options outstanding amounted to $0.4 million, which is expected to be recognized over a weighted-average period of 1.29 years.

The assumptions for volatility, expected life, dividend yield and risk-free interest rate are presented in the table below:

	For the Year Ended December 31,	
	2024	2023
Risk-free interest rate	3.70 – 4.09%	3.51 – 4.01%
Expected life in years	5.04-6.06	5.06 – 6.25
Expected volatility	112.17 -170.50%	89.69 – 112.12%
Expected dividend yield	—%	—%

Restricted Stock

During the year ended December 31, 2023, 3,332 restricted shares vested with a weighted average exercise price of $179.4 and 2,928 restricted shares were cancelled with a weighted average exercise of $246.00. No restricted shares remained unvested at December 31, 2023.

For the year ended December 31, 2024 and 2023 the Company did not issue shares of restricted stock.

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 $0.0 million to the 401(k) Plan during the year ended December 31, 2024 and $0.2 million during the year ended December 31, 2023.

15. Segment Information

The CODM for the Company is the Chief Executive Officer (the "CEO"). The Company’s CEO reviews operating results on an aggregate basis and manages the Company’s operations as a whole for the purpose of evaluating financial performance and allocating resources. This decision-making process reflects the way in which financial information is regularly reviewed and used by the CODM to evaluate performance, set

operational targets, forecast future financial results, and allocate resources. Accordingly, the Company has determined that it has a single reportable and operating segment related to biopharmaceutical research and development.

The Company's CODM assesses financial performance and allocates resources based on consolidated operating results which are also reported on the consolidated statements of operations. The measure of segment assets is reported on the balance sheet as total consolidated assets. The CODM utilizes consolidated operating results by comparing actual results against budgeted amounts. As part of this process, consolidated net loss is a critical performance measure used to evaluate the Company's operating performance and guide strategic decisions and resource allocations, including additional investments in research and development. The table below provides information about the Company's revenue, significant segment expenses and other segment expenses.

The table below provides information about the Company's revenue, significant segment expenses and other segment expenses.

	For the Years Ended December 31,	
($ in thousands)	**2024**	**2023**
Revenues	$ 10	$ 5
Less segment expenses:		
Research and development	340	16,279
General and administrative	4,436	12,219
Gain on lease modification	-	(298)
Restructuring costs	-	1,269
Property and equipment and right-of-use asset impairment	-	4,803
Total operating and segment expense	4,776	34,272
Plus:		
Interest expense	-	(1,921)
Other income, net	133	1,048
Segment Net loss	$ (4,633)	$ (35,140)

16. Subsequent Events

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

Exhibit 10.59

CONSULTING AGREEMENT

This Consulting Agreement (this "Agreement"), dated as of November 14, 2023, is made by and between Alaunos Therapeutics, Inc. (the "Company") and Melinda Lackey ("Consultant"), (together the "Parties").

W I T N E S S E T H :

WHEREAS, the Company desires to engage Consultant to provide services pursuant to the terms and conditions contained in this Agreement; and

WHEREAS, Consultant desires to accept such engagement pursuant to the terms and conditions contained in this Agreement;

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

1. Term. Consultant's services relationship with the Company will commence on November 16, 2023 (the "Start Date") and will continue indefinitely until terminated in accordance with this Section 1. Either party may terminate this Agreement by providing the other party with at least thirty (30) days of advance written notice of such decision. The period of Consultant's services relationship with the Company, beginning on the Start Date, is referred to as the "Term."

2. Services. During the Term, Consultant will be responsible for providing the Company with the services set forth on Exhibit A hereto and such other services as the Parties may agree to from time to time (the "Services"). Consultant may not subcontract or otherwise delegate Consultant's obligations under this Agreement without the Company's prior written consent.

3. Compensation.

(a) Service Fee. As sole compensation for the performance of the Services, the Company will pay to Consultant the amount(s) and on the schedule specified in Exhibit B hereto.

(b) No Withholdings. Consultant acknowledges that the Company does not intend to make withholdings from any payments hereunder. Consultant will have the exclusive responsibility for paying any taxes (including income taxes, social security contributions, and similar obligations) on such payments. At the appropriate time, the Company will provide Consultant with a Form 1099 for Consultant's tax purposes.

(d) No Benefits. The Company will not provide Consultant with any benefits except as provided in this Agreement, nor will Consultant be entitled to participate in any benefit plan or arrangement of the Company or any affiliated entity of the Company, including without limitation any vacation benefit or insurance arrangement (the "Company Benefit Plans").

4. Independent Contractor Status. Consultant acknowledges that, during the Term, Consultant's relationship with the Company will be that of an independent contractor, and not that of an employee of the Company. Nothing herein will be deemed to establish a partnership, joint venture, or employment relationship between the parties.

5. Existing Obligations. This Agreement supplements and does not amend the responsibilities of the Parties with respect to agreements regarding confidential information, trade secrets, or invention or intellectual property assignment, including that certain Invention, Non-Disclosure, and Non-Solicitation Agreement dated November 17, 2021.

6. Notices. All notices and other communications provided for in this Agreement shall be in writing and shall be deemed to have been duly given (a) when delivered and received by the other party, or (b) two (2) business days after being sent when sent by recognized overnight courier to the following addresses:

if to the Company:

Alaunos Therapeutics, Inc.
2617 Bissonnet St., Suite 225
Houston TX 77005
Attention: legalteam@alaunos.com;

if to Consultant:

Melinda Lackey
mlackey@alaunos.com;

or to such other address as either party will have furnished to the other in writing in accordance with this Section 6, except that such notice of change of address shall be effective only upon receipt.

7. D&O Insurance. The Company has obtained and shall cause to be maintained in effect during the Term of this Agreement, with financially sound insurers, a policy of directors' and officers' liability insurance (the "D&O Policy"). The Company and Consultant acknowledge and agree that, in providing the Services, Consultant will act as an officer of the Company, and the Company and Consultant expect and intend that Consultant shall be covered by the D&O policy under no less favorable terms than any other individual covered by the D&O policy. The provisions in this Section 7 shall survive the termination of this Agreement.

8. Indemnification.

(a) The Company shall defend and indemnify Consultant, to the fullest extent permitted by law against any and all threatened, pending, or completed action, suit, proceeding, or alternative dispute resolution mechanism, whether civil, criminal, administrative, arbitrative, investigative, or other, and whether made pursuant to federal, state, or other law (each, a "Claim") against Consultant as a result of the Consultant's performance of the Services or as result of the Consultant's prior work as an employee and officer of the Company, including without limitation Claims brought by or in

the right of the Company, Claims brought by third parties, and Claims in which Consultant is solely a witness.

(b) Consultant shall have the right to advancement by the Company, prior to the final disposition of any Claim by final adjudication to which there are no further rights of appeal, of any and all Expenses (as that term is defined below) actually and reasonably paid or incurred by Consultant in connection with any Claim. Consultant's right to such advancement is not subject to the satisfaction of any standard of conduct. Without limiting the generality or effect of the foregoing, within ten (10) days after any written request by Consultant, the Company shall, in accordance with such request, (a) pay such Expenses on behalf of Consultant, (b) advance to Consultant funds in an amount sufficient to pay such Expenses, or (c) reimburse Consultant for such Expenses. "Expenses" means any and all expenses, including attorneys' and experts' fees, court costs, transcript costs, travel expenses, duplicating, printing, and binding costs, telephone charges, and all other costs and expenses incurred in connection with investigating, defending, being a witness in, or participating in (including on appeal), or preparing to defend, be a witness in, or participate in, any Claim.

(c) Without limiting the generality or effect of the foregoing, Consultants right to indemnification and advancement of Expenses shall be no less favorable than that of any officer of the Company.

(d) The provisions in this Section 8 shall survive the termination of this Agreement.

9. Miscellaneous.

(a) In the event that any of the provisions of this Agreement, or the application of any such provisions to Consultant or the Company with respect to obligations hereunder, is held to be unlawful or unenforceable by any court, then the remaining portions of this Agreement shall remain in full force and effect and shall not be invalidated or impaired in any manner.

(b) No waiver by any party of the breach of any term or covenant contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such breach, or a waiver of any other term or covenant contained in this Agreement.

(c) This Agreement (including all Exhibits hereto) contains the entire agreement between Consultant and the Company with respect to the subject matter of this Agreement (including all Exhibits hereto), and supersedes any and all prior agreements and understandings, whether verbal or written, between Consultant and the Company with respect to the subject matter of this Agreement (including all Exhibits hereto). This Agreement may be amended only by an agreement in writing signed by Consultant and the Company.

(d) This Agreement may not be assigned by Consultant or the Company without the other party's consent, and any such attempted assignment shall be void and of no effect.

(e) The terms and language of this Agreement are the result of arm's length negotiations between the parties. Consequently, there shall be no presumption that any ambiguity in this Agreement should be resolved in favor of one party and against another. Any controversy

concerning the construction of this Agreement shall be decided neutrally without regard to authorship.

(f) The titles and headings of sections and subsections contained in this Agreement are included solely for convenience of reference and will not control the meaning or interpretation of any of the provisions of this Agreement.

(g) This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute but one agreement. Each party may execute this Agreement in Adobe Portable Document Format or in a similar format ("PDF") sent by electronic mail. In addition, PDF signatures of authorized signatories of any party will be deemed to be original signatures and will be valid and binding, and delivery of a PDF signature by any party will constitute due execution and delivery of this Agreement.

(h) This Agreement shall be governed by, and construed in accordance with, the laws of Texas, without giving effect to its conflict of laws principles.

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

ALAUNOS THERAPEUTICS, INC. **CONSULTANT**

By: /s/ Michael Wong
Name: Michael Wong
Title: Vice President, Finance

By: /s/ Melinda Lackey
Name: Melinda Lackey

EXHIBIT A

Description of Services

Consultant shall provide legal, corporate and administrative services to the Company and other services as may be requested by the Company.

EXHIBIT B

Service Fee

(a) Service Fee: $ 400 per hourly rate paid in U.S. dollars by the Company to Consultant for the entire Term of this Agreement, unless otherwise agreed by the Company and Consultant in writing.

(b) Expenses: The Company will reimburse Consultant for any usual and customary business expenses as may be reasonably required to provide the services to the Company for the term of this Agreement (e.g. office supplies, travel time and mileage).

(c) Payments to Consultant: Consultant will provide the Company a Statement of Services rendered, including hourly fees and expenses, every bi-weekly period during the Term of this Agreement. The payments for Statement of Services rendered will be delivered to Consultant within ten (10) business days upon receipt of the Statement of Services by the Company during the term of this Agreement.

Exhibit 10.60

December 20, 2023

Dear Kevin,

This Separation and Release Agreement ("Agreement") follows up on our recent discussions concerning the termination of your employment with Alaunos Therapeutics, Inc. (the "Company"). To assist you in your transition, the Company is offering you certain transitional benefits in exchange for a mutual, general release of claims and other terms set forth below.

The specific terms of the Agreement are as follows:

1. Termination of Employment. Effective December 22, 2023, you will be relieved of all duties and not required to perform any additional services, you will be paid through and including December 22, 2023, which shall be your last day of employment with the Company (the "Separation Date"). The Company will pay you all wages earned and any accrued and unused PTO in accordance with the Company's policies through your Separation Date. You will receive these amounts regardless of whether you sign this Agreement.

2. Separation Pay.

(a) In consideration for your execution of and compliance with this Agreement, provided that you execute, return, and do not revoke this Agreement pursuant to Section 11, you shall receive a one-time lump sum separation payment representing six (6) months of your base salary and six (6) months of COBRA eligibility reflecting the same coverage as you currently hold with the Company (the "Separation Payment"), less all applicable income and payroll taxes, deductions and withholdings. The Separation Payment shall be paid to you on the next regularly scheduled pay day following the Effective Date (as that term is defined below) of this Agreement.

(b) The Company reserves the right to withhold from any payments (including but not limited to the Separation Payment) to you all sums that it is required or allowed to withhold pursuant to applicable tax withholding laws or regulations. You shall remain solely responsible for any and all income or other taxes due by you or assessed against you on payments made to you.

3. Benefits.

(a) Healthcare Continuation Coverage. If applicable, your healthcare coverage will cease as of the last day of the month in which the employment separation occurs. However, you may be eligible to continue health insurance coverage at your own expense pursuant to the Consolidated Omnibus Budget Reconciliation Act ("COBRA"). Pursuant to COBRA, if you are eligible, you will be notified of the procedures to access health care continuation coverage by separate correspondence. All other employee benefits will terminate effective on your Separation Date.

(b) Unemployment Compensation. The Company agrees that if you decide to seek unemployment compensation benefits, it will not contest your application for

unemployment compensation. The Company, however, will not provide any false information to any state agency. The Company makes no representations concerning your eligibility for unemployment compensation. You acknowledge and understand that any determination as to your eligibility for unemployment compensation is made solely by the state agency to which you apply for such benefits.

(c) Other Benefits. Except as specifically set forth in this Agreement, and except as to any vested benefits, your right to, and participation in, all employee benefit plans of the Company shall terminate as of your Separation Date in accordance with the specific terms of each plan. To the extent you have any vested assets in any employee benefit plan of the Company, the status and treatment of any such assets shall be governed by the applicable terms of such plan.

4. Acknowledgements. You acknowledge and agree that:

(a) this Agreement and the Separation Payment are neither intended to nor shall constitute a severance plan and shall confer no benefit on anyone other than the Company and you; and

(b) except for (i) any unpaid regular wages (including accrued but unused vacation time) earned through (and including) the Separation Date, which shall be paid by the Company and (ii) any vested monies due to you pursuant to any retirement programs in which you participate, you have been paid and provided (or will be paid and provided by December 31, 2023) all wages, vacation pay, holiday pay, earned paid sick time, PTO, family and medical leave, bonuses, commissions and any other form of compensation or benefit that may be due to you now or which would have become due in the future in connection with your employment with or separation of employment from the Company.

5. Return of Company Property. Except as agreed to for fulfillment of services under any consulting agreement entered into by you and the Company, you agree to relinquish access to or return to the Company, and agree that you will knowingly retain no copies of: (a) all originals and copies of any proprietary or confidential information and trade secrets of the Company, whether in print, electronic or other form; (b) all originals and copies of Company and customer files, written materials, records and other documents, whether in print, electronic or other form, whether made by you or coming into your possession during the course of your employment with the Company; (c) all identification cards, keys, security passes or other means of access to Company facilities; and (d) any credit cards, or telephone cards. All such property must be returned on or before your Separation Date or the expiration of any consulting agreement, whichever is later. In addition, on the Separation Date or the expiration of any consulting agreement, whichever is later, you will factory-reset your company laptop and company iPhone and ensure all data is deleted. After such deletion, you are permitted to retain this laptop and iPhone.

6. Confidentiality.

(a) You understand that nothing in this Agreement shall limit the rights of any government agency or entity or any party's right of access to, participation or cooperation

with any government agency or entity including, but not limited to, the Department of Justice, the Securities and Exchange Commission, Congress, and any agency Inspector General, nor shall anything in this Agreement limit your ability to make any other disclosures that are protected under the whistleblower provisions of federal law or regulation. You understand that you do not need the prior authorization of the Company to make any such reports or disclosures and that you are not required to notify the Company that you have made such reports or disclosures.

(b) You agree to abide by any applicable common law and/or statutory obligations relating to the protection and non-disclosure of the Company's trade secrets and/or confidential and proprietary documents and information, and you specifically agree that you will not disclose any confidential or proprietary information that you acquired as an employee of the Company to any other person or entity, or use such information in any manner that is detrimental to the interests of the Company.

(c) Defend Trade Secrets Act Notice**:** Notwithstanding your confidentiality and nondisclosure obligations, you are hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

7. Transition and Cooperation. Following the Separation Date, you agree to make yourself reasonably available to the Company to provide any information related to the transition of your duties. You further agree to reasonably cooperate with and assist the Company as reasonably requested by the Company, with respect to any investigation, litigation, proceeding, arbitration or other formal or informal dispute resolution effort in which you are or have had involvement, is in regard to events that occurred during your tenure with the Company, or with respect to which you have relevant information by being reasonably available (i) to consult with the Company's counsel, and (ii) for interviews, depositions and/or testimony in regard to any such matters, except with respect to any such matter to which you are or may become a party.

8. Non-Filing of Complaint or Charges. You represent that you have not filed or asserted any cause of action, claim, charge or other action or proceeding against the Company.

9. No Knowledge of Misconduct. You represent that during the term of your employment with the Company, you have at all times conducted yourself in a lawful manner and that you are unaware of any act or omission on your part or the part of the Company that may constitute a violation of any law, regulation, or order, nor do you know of any basis on which any third party or governmental entity could assert such a claim. This expressly includes any and all conduct that potentially could give rise to claims under the Sarbanes-Oxley Act of 2002. You

further represent that you have disclosed any misconduct of which you are aware, including potential violations of Company policies. You further affirm that you have no information concerning any conduct involving the Company that involves any false claims to the United States.

10.Release of All Claims.

(a) You hereby acknowledge and agree that by signing this Agreement and accepting the Severance Payment, you are waiving your right to assert any form of legal claim against the Company of any kind whatsoever from the beginning of time through and including the date you sign this Agreement, 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") (specifically including any claims of breach of contract whether express or implied, and claims sounding in intentional or unintentional torts such as negligence and fraud, and any statutory or regulatory claims) against the Company 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 the Company up through and including the date you sign this Agreement. You understand that there could be unknown or unanticipated Claims resulting from your employment with the Company and the termination thereof and agree that such Claims are intended to be, and are, included in this waiver and release.

(b) The Company herby acknowledges and agrees that by signing this Agreement and accepting the consideration herein, the Company is waiving its right to assert any form of legal claim against you, Kevin S. Boyle, Sr., of any kind whatsoever from the beginning of time through and including the Separation Date, except for claims related to any failure to perform your obligations under this Agreement. The Company's waiver and release is intended to bar any Claims against you 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, compensatory damages, emotional distress damages, punitive damages, attorneys' fees and any other costs) against you up through and including the Separation Date. The Company understands that there could be unknown or unanticipated Claims resulting from your employment with the Company and the termination thereof and agree that such Claims are intended to be, and are, included in this waiver and release.

(c) 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, and the Company specifically waives and releases you from any Claims arising from or related to your employment relationship with the Company, including without limitation:

i. 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 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 date you sign this Agreement;

ii. 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, and the Family and Medical Leave Act, 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 date you sign this Agreement;

iii. Claims under any local, state or federal common law theory; and

iv. any other Claim arising under other local, state or federal law.

(d) The general release in this Section 10 is not affected or limited by the recitation of the specific releases in this Section 10.

(e) Consistent with federal and state discrimination laws, nothing in this release shall be deemed to 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.

(f) The general release in this Section 10 shall not limit any right you may have to receive a whistleblower award or bounty for information provided to the Securities and Exchange Commission.

11.Important Notice Regarding Release of Claims of Age Discrimination. You acknowledge that you knowingly and voluntarily enter into this Agreement with the purpose of waiving and releasing any age discrimination claims you may have under the Age Discrimination in Employment Act ("ADEA"), including the Older Workers Benefit Protection Act ("OWBPA"), and you acknowledge and agree that:

(a) this Agreement is written in a manner in which you fully understand;

(b) you specifically waive any rights or claims arising under the ADEA;

(c) your agreement to all of the terms set forth in this Agreement is knowing and voluntary;

(d) you are not waiving rights or claims under the ADEA that may arise after the date this Agreement is executed;

(e) the rights and claims waived in this Agreement are in exchange for consideration over and above anything to which you are already entitled;

(f) you have been and are hereby advised in writing to consult with an attorney prior to executing this Agreement, and has, in fact, had an opportunity to do so; and

(g) as required pursuant to the OWBPA, you are being provided with information in **Exhibit A** to this Agreement which employees are eligible for Severance Payment.

12.Time for Acceptance; Effective Date.

(a) You have been given a period of up to forty-five (45) calendar days, if desired, within which to consider this Agreement and, in the event you decide to execute this Agreement in fewer than forty-five (45) calendar days, you acknowledge that you have done so with the express understanding that you have been given and declined the opportunity to consider this Agreement for a full forty-five (45) calendar days. You further acknowledge that your decision to sign the Agreement in fewer than forty-five (45) calendar days was not induced by the Company through fraud, misrepresentation, or a threat to withdraw or alter the offer prior to the expiration of the forty-five (45) day time period.

(b) You have the right to revoke this waiver and release of any claims under the ADEA covered by this Agreement within seven (7) calendar days from the date you execute this Agreement (the "Revocation Period"). This Agreement shall not be effective until such Revocation Period has expired without you having exercised your revocation rights. Thus, this Agreement will become final, binding and enforceable on the eighth (8th) calendar day after you execute and deliver this Agreement to the Company ("the Effective Date"), provided it has not been duly revoked in accordance with the terms herein. Notice of revocation must be made in writing and received by the Company prior to the conclusion of the Revocation Period. In order to constitute notice of acceptance and/or revocation hereunder, such notice must be delivered to Michael Wong, Vice President, Finance at info@alaunos.com.

(c) This Agreement will be null and void and no Separation Payment or other benefit offered to you pursuant to Paragraph 6 above will be paid if: (i) you do not sign it within the forty-five (45) day period, or (iii) you revoke your execution within the Revocation Period.

13.Miscellaneous.

(a) Non-Admission. This Agreement does not constitute an allegation, admission or acknowledgment by any party of any unlawful or improper act or conduct, all of which is expressly denied.

(b) Entire Agreement. This Agreement constitutes the full understanding and entire Agreement between you and the Company and supersedes any other agreements of any kind, whether oral or written, formal or informal; *provided however*, that you shall remain bound by your continuing obligations to preserve the Company's trade secrets, intellectual property, and confidential information, and you and the Company expressly agree that except for the non-competition obligation set forth in Section 3, which the Company hereby waives, the Invention, Non-Disclosure, Non-Solicitation and Non-Competition Agreement that you signed with the Company (a copy of which is provided in your packet) shall remain in full force and effect. The parties represent and acknowledge that in signing this Agreement, each has not relied upon any representation or statement made by the other not set forth in this Agreement.

(c) Waiver. The parties agree that the failure of a party at any time to require performance of any provision of this Agreement shall not affect, diminish, obviate or void in any way the party's full right or ability to require performance of the same or any other provision of this Agreement at any time thereafter.

(d) Successor and Assigns. The rights and benefits of the Company under this Agreement shall be assignable to any successor, related or affiliated entity. All rights and obligations under this Agreement shall inure to the benefit of and be binding upon your successors but shall be personal and non-assignable by you.

(e) Governing Law; Jurisdiction. This Agreement shall be construed in accordance with and governed by the laws of the state of Texas without regard to the conflict of law principles thereof. Both parties agree that any action, demand, claim or counterclaim relating to (i) your employment and separation of your employment, and (ii) the terms and provisions of this Agreement or to its breach, shall be commenced solely and exclusively in the state of Texas in a court of competent jurisdiction.

(f) JURY WAIVER. BOTH PARTIES FURTHER AGREE THAT ANY DISPUTE REGARDING THE COMPLIANCE WITH OR ENFORCEABILITY OF THIS AGREEMENT 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.

(g) Severability. This Agreement is intended to be severable. Should any portion, term or provision of this Agreement be declared or determined by any court to be illegal, invalid or unenforceable, the validity of the remaining portions, terms and provisions, and the application of such portion, term or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected

thereby, and the illegal, invalid or unenforceable portion, term or provision shall be valid and enforceable to the fullest extent permitted by applicable law.

(h) Construction. The headings of the paragraphs of this Agreement are for convenience only and are not binding on any interpretation of this Agreement.

(i) Modifications. No variations or modifications hereof shall be deemed valid unless reduced to writing and signed by the Company and you.

It is the Company's desire and intent to make certain that you fully understand the provisions 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 the provisions and effects of this Agreement and to consult with legal counsel; (b) your agreements and obligations under this Agreement are made voluntarily, knowingly and without duress; and (c) neither the Company nor its agents or representatives have made any representations inconsistent with the provisions of this Agreement.

If you wish to accept this Agreement, please sign and date the Agreement below and return it to me within the time period specified in Section 12.

We wish you every success for the future.

Sincerely,

/s/ Michael Wong
Michael Wong
Vice President, Finance

By signing this Agreement, I state that I have read it, I understand it, I agree with everything in it and I have signed it knowingly and voluntarily under seal.

/s/ Kevin S. Boyle, Sr.

Kevin S. Boyle, Sr.

EXHIBIT A

ADEA WAIVER INFORMATION

a. The applicable business unit is all personnel employed by Alaunos Therapeutics, Inc. (the "Company"), in its Research & Development, General & Admin, and Technical Operations groups.
b. The job titles listed below were selected or not selected for the elimination of their position and offered severance pay. All individuals who are being offered payment of severance, such offer is contingent upon and subject to entering into a Separation and Release Agreement and General Release ("**Separation Agreement**").
c. All persons who are being offered severance subject to a Separation Agreement must sign the Separation Agreement and return it to the Company.
d. The following is a list of the job title and ages of individuals employed by the Company in the applicable Research & Development, General & Admin, and Technical Operations groups who were and were not selected for the offer of severance in exchange for entering into a Separation Agreement:

JOB TITLES AND AGES OF EMPLOYEES SELECTED FOR TERMINATION AND ELIGIBLE FOR SEVERANCE PAYMENT OFFER

JOB TITLE	**AGES**
Chief Executive Officer	50

JOB TITLES AND AGES OF EMPLOYEES NOT SELECTED FOR TERMINATION AND ARE INELIGIBLE FOR SEVERANCE PAYMENT OFFER

JOB TITLE	**AGES**
Vice President	43

Exhibit 10.61

CONSULTING AGREEMENT

This Consulting Agreement (this "Agreement"), dated as of December 22, 2023, is made by and between Alaunos Therapeutics, Inc. (the "Company") and Kevin S. Boyle Sr. ("Consultant").

W I T N E S S E T H :

WHEREAS, the Company desires to engage Consultant to provide services pursuant to the terms and conditions contained in this Agreement; and

WHEREAS, Consultant desires to accept such engagement pursuant to the terms and conditions contained in this Agreement;

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

1. Term. Consultant's services relationship with the Company will commence on January 1, 2024 (the "Start Date") and will continue for a period of six (6) months. The period of Consultant's services relationship with the Company, beginning on the Start Date, is referred to as the "Term."

2. Services. During the term, Consultant will be responsible for providing the Company with the services set forth on Exhibit A hereto and such other services as the parties may agree to from time to time (the "Services"). Consultant may not subcontract or otherwise delegate Consultant's obligations under this Agreement without the Company's prior written consent. While providing the Services, the Consultant will not have specified hours but will be required to make himself reasonably available. The Company shall provide electronic access to Company systems and facilities to facilitate Consultant's services, including email.

3. Non-Exclusivity. Nothing in this Agreement shall prevent Contractor from seeking or accepting other employment, consulting engagements, or board positions with other companies or organizations, provided that such activities do not (i) create a conflict of interest with the Company's business or the Services; or (ii) violate any confidentiality obligations owed by the Contractor to the Company under this or any other agreement.

4. Compensation.

(a) Service Fee. As sole compensation for the performance of the Services, the Company will pay to Consultant the amount(s) and on the schedule specified in Exhibit B hereto.

(b) No Withholdings. Consultant acknowledges that the Company does not intend to make withholdings from any payments hereunder. Consultant will have the exclusive

responsibility for paying any taxes (including income taxes, social security contributions, and similar obligations) on such payments. At the appropriate time, the Company will provide Consultant with a Form 1099 for Consultant's tax purposes.

(c) No Benefits. The Company will not provide Consultant with any benefits except as provided in this Agreement, nor will Consultant be entitled to participate in any benefit plan or arrangement of the Company or any affiliated entity of the Company, including without limitation any vacation benefit or insurance arrangement (the "Company Benefit Plans").

5. Independent Contractor Status. Consultant acknowledges that, during the Term, Consultant's relationship with the Company will be that of an independent contractor, and not that of an employee of the Company. Nothing herein will be deemed to establish a partnership, joint venture, or employment relationship between the parties.

6. Existing Obligations. This Agreement supplements and does not amend the responsibilities of the Parties with respect to agreements regarding confidential information, trade secrets, or invention or intellectual property assignment.

7. Notices. All notices and other communications provided for in this Agreement shall be in writing and shall be deemed to have been duly given (a) when delivered and received by the other party, or (b) two (2) business days after being sent when sent by recognized overnight courier to the following addresses:

if to the Company:

Alaunos Therapeutics, Inc.
2617 Bissonnet, Suite 225
Houston TX 77054
Attention: Legal Team
Email: legalteam@alaunos.com;

if to Consultant:

Kevin S. Boyle, Sr.

or to such other address as either party will have furnished to the other in writing in accordance with this Section 7, except that such notice of change of address shall be effective only upon receipt.

8. D&O Insurance. The Company has obtained and shall cause to be maintained in effect during the Term of this Agreement, with financially sound insurers, a policy of directors' and officers' liability insurance (the "D&O Policy"). The Company and Consultant acknowledge and agree that, in providing the Services, Consultant will act as an officer of the Company, and the Company and Consultant expect and intend that Consultant shall be covered by the D&O policy

under no less favorable terms than any other individual covered by the D&O policy. The provisions in this Section 8 shall survive the termination of this Agreement.

9. Indemnification.

(a) The Company shall defend and indemnify Consultant, to the fullest extent permitted by law against any and all threatened, pending, or completed action, suit, proceeding, or alternative dispute resolution mechanism, whether civil, criminal, administrative, arbitrative, investigative, or other, and whether made pursuant to federal, state, or other law (each, a "Claim") against Consultant as a result of the Consultant's performance of the Services or as result of the Consultant's prior work as an employee and officer of the Company, including without limitation Claims brought by or in the right of the Company, Claims brought by third parties, and Claims in which Consultant is solely a witness.

(b) Consultant shall have the right to advancement by the Company, prior to the final disposition of any Claim by final adjudication to which there are no further rights of appeal, of any and all Expenses (as that term is defined below) actually and reasonably paid or incurred by Consultant in connection with any Claim. Consultant's right to such advancement is not subject to the satisfaction of any standard of conduct. Without limiting the generality or effect of the foregoing, within ten (10) days after any written request by Consultant, the Company shall, in accordance with such request, (i) pay such Expenses on behalf of Consultant, (ii) advance to Consultant funds in an amount sufficient to pay such Expenses, or (iii) reimburse Consultant for such Expenses. "Expenses" means any and all expenses, including attorneys' and experts' fees, court costs, transcript costs, travel expenses, duplicating, printing, and binding costs, telephone charges, and all other costs and expenses incurred in connection with investigating, defending, being a witness in, or participating in (including on appeal), or preparing to defend, be a witness in, or participate in, any Claim.

(c) Without limiting the generality or effect of the foregoing, Consultants right to indemnification and advancement of Expenses shall be no less favorable than that of any officer of the Company.

(d) The provisions in this Section 9 shall survive the termination of this Agreement.

10. Miscellaneous.

(a) In the event that any of the provisions of this Agreement, or the application of any such provisions to Consultant or the Company with respect to obligations hereunder, is held to be unlawful or unenforceable by any court, then the remaining portions of this Agreement shall remain in full force and effect and shall not be invalidated or impaired in any manner.

(b) No waiver by any party of the breach of any term or covenant contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such breach, or a waiver of any other term or covenant contained in this Agreement.

(c) This Agreement (including all Exhibits hereto) contains the entire agreement between Consultant and the Company with respect to the subject matter of this Agreement

(including all Exhibits hereto), and supersedes any and all prior agreements and understandings, whether verbal or written, between Consultant and the Company with respect to the subject matter of this Agreement (including all Exhibits hereto). This Agreement may be amended only by an agreement in writing signed by Consultant and the Company.

(d) This Agreement may not be assigned by Consultant or the Company without the other party's consent, and any such attempted assignment shall be void and of no effect.

(e) The terms and language of this Agreement are the result of arm's length negotiations between the parties. Consequently, there shall be no presumption that any ambiguity in this Agreement should be resolved in favor of one party and against another. Any controversy concerning the construction of this Agreement shall be decided neutrally without regard to authorship.

(f) The titles and headings of sections and subsections contained in this Agreement are included solely for convenience of reference and will not control the meaning or interpretation of any of the provisions of this Agreement.

(g) This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute but one agreement. Each party may execute this Agreement in Adobe Portable Document Format or in a similar format ("PDF") sent by electronic mail. In addition, PDF signatures of authorized signatories of any party will be deemed to be original signatures and will be valid and binding, and delivery of a PDF signature by any party will constitute due execution and delivery of this Agreement.

(h) This Agreement shall be governed by, and construed in accordance with, the laws of Texas, without giving effect to its conflict of laws principles.

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

ALAUNOS THERAPEUTICS, INC.	**CONSULTANT**
By: _/s/ Michael Wong_____	__/s/ Kevin S. Boyle Sr._____
Name: Michael Wong	Name: Kevin S. Boyle Sr.
Title: Vice President, Finance	

EXHIBIT A

Description of Services

The Consultant, in their capacity as a former CEO, will provide the following Services:

(a) **Strategic Advisory:** The Consultant will provide strategic advice and insights based on their experience and knowledge of the Company's operations, industry trends, and competitive landscape.

(b) **Other Services:** The Consultant will perform other services as mutually agreed upon between the Company and the Consultant from time to time.

The Consultant agrees to provide the Services in a professional and diligent manner, consistent with industry standards and in compliance with the Company's policies and procedures. The Consultant may not subcontract or otherwise delegate their obligations under this Agreement without the Company's prior written consent. While providing the Services, the Consultant will not have specified hours but will be required to make themselves reasonably available.

EXHIBIT B

Service Fee

(a) Service Fee: $15,000.00 per month paid in U.S. dollars by the Company to Consultant for the entire Term of this Agreement, unless otherwise agreed by the Company and Consultant in writing, payable at the beginning of each month with no invoice required from Consultant.

(b) Expenses: The Company will reimburse Consultant for any usual and customary business expenses as may be reasonably required to provide the services to the Company for the term of this Agreement (e.g. office supplies, travel time and mileage).

Exhibit 10.62

CONSULTING AGREEMENT

This Consulting Agreement (this "Agreement"), dated as of February 22, 2024, is made by and between Alaunos Therapeutics, Inc. (the "Company") and Ferdinand Groenewald ("Consultant"), (together the "Parties").

W I T N E S S E T H :

WHEREAS, the Company desires to engage Consultant to provide services pursuant to the terms and conditions contained in this Agreement; and

WHEREAS, Consultant desires to accept such engagement pursuant to the terms and conditions contained in this Agreement;

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

1. Term. Consultant's services relationship with the Company will commence on Thursday, February 22, 2023 (the "Start Date") and will continue indefinitely until terminated in accordance with this Section 1. Either party may terminate this Agreement by providing the other party with at least thirty (30) days of advance written notice of such decision. The period of Consultant's services relationship with the Company, beginning on the Start Date, is referred to as the "Term."

2. Services. During the Term, Consultant will be responsible for providing the Company with the services set forth on Exhibit A hereto and such other services as the Parties may agree to from time to time (the "Services"). Consultant may not subcontract or otherwise delegate Consultant's obligations under this Agreement without the Company's prior written consent.

3. Compensation.

(a) Service Fee. As sole compensation for the performance of the Services, the Company will pay to Consultant the amount(s) and on the schedule specified in Exhibit B hereto.

(b) No Withholdings. Consultant acknowledges that the Company does not intend to make withholdings from any payments hereunder. Consultant will have the exclusive responsibility for paying any taxes (including income taxes, social security contributions, and similar obligations) on such payments. At the appropriate time, the Company will provide Consultant with a Form 1099 for Consultant's tax purposes.

(d) No Benefits. The Company will not provide Consultant with any benefits except as provided in this Agreement, nor will Consultant be entitled to participate in any benefit plan or arrangement of the Company or any affiliated entity of the Company, including without limitation any vacation benefit or insurance arrangement (the "Company Benefit Plans").

4. Independent Contractor Status. Consultant acknowledges that, during the Term, Consultant's relationship with the Company will be that of an independent contractor, and not that of an employee of the Company. Nothing herein will be deemed to establish a partnership, joint venture, or employment relationship between the parties.

5. Confidentiality. Consultant acknowledges and agrees that this Agreement creates a relationship of confidence and trust on the part of Consultant as Consultant provides Services for the benefit of the Company. In the performance of Consultant's obligations under this Agreement, Consultant and its principals, agents, employees and contractors may receive, create for the Company and/or have access to, among other things, technical, customer, personnel and business information in written, graphic, oral or other tangible forms such as specifications, records, data, computer programs, drawings, models, reports and samples (collectively referred to as "Confidential Information") owned or controlled by the Company. Such Confidential Information contains material that is proprietary or confidential, or material that is protected by applicable laws regarding secrecy of communications or trade secrets. Accordingly:

(a) Consultant recognizes and agrees that nothing in this Agreement will be construed as granting any rights, by license or otherwise, to any Confidential Information or to any inventions or patents, trade secrets, copyrights, trademarks, or other intellectual property right that has issued or that may issue based on such Confidential Information. All Confidential Information (including all copies thereof) will at all times remain the property of the Company and will be immediately returned to the Company after Consultant's need for it has expired, or upon request of the Company, and in any event, upon completion or termination of the Services to be provided by Consultant. At such time, Consultant shall also erase, delete, or destroy any notes, documents, magnetic media or other computer storage, including system backups, which contain any Confidential Information.

(b) Consultant will advise its principals, employees, agents and contractors who might have access to Confidential Information of the confidential nature thereof and agrees that its employees will be bound by the terms of this Agreement. Consultant will not disclose any Confidential Information to any employee except for those persons who have a need for such information in connection with Consultant rendering the Services and who agree in writing to bound by the provision of this Agreement, nor will it disclose any Confidential Information to any third party without first obtaining the Company's express written consent, which may be withheld in the sole discretion of the Company. For the purposes of this Sub- section (b), the term "employee" will include, in addition to employees, directors, officers, members, owners, independent contractors, consultants, collaborators and other agents of the Consultant.

(c) The term "Confidential Information" will not include information that Consultant can establish (i) was publicly known and made generally available in the public domain prior to the time of disclosure to Consultant; (ii) becomes publicly known and made generally available after disclosure to Consultant through no action or inaction of Consultant; (iii) is in the possession of Consultant, without confidentiality restrictions, at the time of disclosure by the Company, as shown by Consultant's files and records immediately prior to the time of disclosure; or (iv) is approved for release by the Company in writing. Moreover, this confidentiality restriction shall not apply to information that is required by law or regulation or required pursuant to a valid order of a court or regulatory agency to be disclosed by Consultant, but only to the limit and extent of such required disclosure, provided that, prior to such disclosure, Consultant provides the Company with prompt written notice of such requirement and the facts and circumstances concerning such requirement and assists the Company in obtaining an order or orders protecting the information from any disclosure or limiting the extent of information to be disclosed.

6. Intellectual Property Rights.

(a) (a) It is the intention of the parties that the Company should own the rights in any materials and work product resulting from the Services. To that end, Consultant shall on the Company's written request from time to time sign an unconditional assignment with full title guarantee of all rights in any such materials as are owned by Consultant and capable of assignment. Consultant shall also waive any moral rights it may have in the any materials created by Consultant for Company when providing Services.

(b) In addition, any information, know-how, data, results, and inventions, and any associated intellectual property, that is made, discovered, created, invented or generated by Consultant in any activities or work under this Agreement shall be owned by the Company.

(c) Consultant acknowledges that the Company does not desire to acquire any trade secrets, know-how, confidential information, or other intellectual property that Consultant may have acquired from or developed for any third parties. In the course of providing the Services, Consultant shall not use or disclose any third party intellectual property, including without limitation any intellectual property of (i) any former or current employer, (ii) any person for whom Consultant has performed or currently performs consulting services, or (iii) any other person to whom Consultant has a legal obligation regarding the use or disclosure of such intellectual property.

(d) Consultant agrees to assist in any logistics of future intellectual property that is generated from this Agreement as needed and determined by Consultant, with no compensation solely for such participation, including but not limited signing assignment forms, inventor forms, and advising on substantive matters as needed by and when requested by the Company. Company agrees to pay for any associated expenses, fees, and further patent prosecution.

7. Notices. All notices and other communications provided for in this Agreement shall be in writing and shall be deemed to have been duly given (a) when delivered and received by the other party, or (b) two (2) business days after being sent when sent by recognized overnight courier to the following addresses:

if to the Company:

Alaunos Therapeutics, Inc.
2617 Bissonnet St., Suite 225
Houston TX 77005
Attention: legalteam@alaunos.com;

if to Consultant:

Ferdinand Groenewald

or to such other address as either party will have furnished to the other in writing in accordance with this Section 6, except that such notice of change of address shall be effective only upon receipt.

D&O Insurance. The Company has obtained and shall cause to be maintained in effect during the Term of this Agreement, with financially sound insurers, a policy of directors' and officers' liability insurance (the "D&O Policy"). The Company and Consultant acknowledge and agree that, in providing the Services, Consultant will act as an officer of the Company, and the Company and Consultant expect and intend that Consultant shall be covered by the D&O policy under no less favorable terms than any other individual covered

by the D&O policy. The provisions in this Section 7 shall survive the termination of this Agreement.

8. Indemnification.

(a) The Company shall defend and indemnify Consultant, to the fullest extent permitted by law against any and all threatened, pending, or completed action, suit, proceeding, or alternative dispute resolution mechanism, whether civil, criminal, administrative, arbitrative, investigative, or other, and whether made pursuant to federal, state, or other law (each, a "Claim") against Consultant as a result of the Consultant's performance of the Services or as result of the Consultant's prior work as an employee and officer of the Company, including without limitation Claims brought by or in the right of the Company, Claims brought by third parties, and Claims in which Consultant is solely a witness.

(b) Consultant shall have the right to advancement by the Company, prior to the final disposition of any Claim by final adjudication to which there are no further rights of appeal, of any and all Expenses (as that term is defined below) actually and reasonably paid or incurred by Consultant in connection with any Claim. Consultant's right to such advancement is not subject to the satisfaction of any standard of conduct. Without limiting the generality or effect of the foregoing, within ten (10) days after any written request by Consultant, the Company shall, in accordance with such request, (a) pay such Expenses on behalf of Consultant, (b) advance to Consultant funds in an amount sufficient to pay such Expenses, or (c) reimburse Consultant for such Expenses. "Expenses" means any and all expenses, including attorneys' and experts' fees, court costs, transcript costs, travel expenses, duplicating, printing, and binding costs, telephone charges, and all other costs and expenses incurred in connection with investigating, defending, being a witness in, or participating in (including on appeal), or preparing to defend, be a witness in, or participate in, any Claim.

(c) Without limiting the generality or effect of the foregoing, Consultants right to indemnification and advancement of Expenses shall be no less favorable than that of any officer of the Company.

(d) The provisions in this Section 8 shall survive the termination of this Agreement.

9. Miscellaneous.

(a) In the event that any of the provisions of this Agreement, or the application of any such provisions to Consultant or the Company with respect to obligations hereunder, is held to be unlawful or unenforceable by any court, then the remaining portions of this Agreement shall remain in full force and effect and shall not be invalidated or impaired in any manner.

(b) No waiver by any party of the breach of any term or covenant contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such breach, or a waiver of any other term or covenant contained in this Agreement.

(c) This Agreement (including all Exhibits hereto) contains the entire agreement between Consultant and the Company with respect to the subject matter of this Agreement (including all Exhibits hereto), and supersedes any and all prior agreements and understandings, whether verbal or written, between Consultant and the Company with respect to the subject matter

of this Agreement (including all Exhibits hereto). This Agreement may be amended only by an agreement in writing signed by Consultant and the Company.

(d) This Agreement may not be assigned by Consultant or the Company without the other party's consent, and any such attempted assignment shall be void and of no effect.

(e) The terms and language of this Agreement are the result of arm's length negotiations between the parties. Consequently, there shall be no presumption that any ambiguity in this Agreement should be resolved in favor of one party and against another. Any controversy concerning the construction of this Agreement shall be decided neutrally without regard to authorship.

(f) The titles and headings of sections and subsections contained in this Agreement are included solely for convenience of reference and will not control the meaning or interpretation of any of the provisions of this Agreement.

(g) This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, and such counterparts shall together constitute but one agreement. Each party may execute this Agreement in Adobe Portable Document Format or in a similar format ("PDF") sent by electronic mail. In addition, PDF signatures of authorized signatories of any party will be deemed to be original signatures and will be valid and binding, and delivery of a PDF signature by any party will constitute due execution and delivery of this Agreement.

(h) This Agreement shall be governed by, and construed in accordance with, the laws of Texas, without giving effect to its conflict of laws principles.

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

ALAUNOS THERAPEUTICS, INC. **CONSULTANT**

By: /s/ Dale Curtis Hogue, Jr. /s/ Ferdinand Groenewald
Name: Dale Curtis Hogue, Jr. Name: Ferdinand Groenewald
Title: CEO (interim)

EXHIBIT A

Description of Services

Consultant shall lead the accounting and financial reporting function of the Company. Consultant will work directly with the Board of Directors, Company employees and other consultants to ensure proper and complete monthly / quarterly close processes. Consultant will partner with the business in making decisions and promoting continuous improvement. This is a hands-on role that reports directly to the CEO and Board Chair. Further specific responsibilities will include, but not be limited to the following:

- Lead accounting and financial reporting activities of the Company in accordance with U.S. GAAP and SEC requirements
- Ensure effective financial close process and timely SEC filings (10-Q, 10-K, 8-K, registration statements, etc.)
- Serve as Principal Accounting Officer for the Company
- Prepare or review general ledger account reconciliations, including journal entries and supporting documentation, to validate accuracy of reported balances
- Responsible for maintaining a strong public company internal control environment in accordance with the provisions of the Sarbanes-Oxley Act within the accounting and reporting function
- Serve as U.S. GAAP technical resource, including literature research and application to transactions or processes
- Liaise with external tax consultants to ensure compliance with all tax jurisdictions
- Review and update accounting policies and procedures to ensure compliance with U.S. GAAP, including the adoption of new accounting pronouncements
- Serve as key contact with internal and external auditors
- Prepare and present Audit Committee / Board of Directors materials and communications
- Manage the treasury function
- Equity management with transfer agent and awards in Certent (equity management tool)
- Motivated in taking on tasks beyond formal job responsibilities and ability to work in a dynamic and changing environment
- Approve and pay invoices and payroll; ability to execute accounts payable function

- Drive the timing for monthly billing and other cash management and expense management techniques
- Ongoing financial planning and analysis and financial forecasting processes
- Evaluate and present period end analytical reviews of financial information
- Provide ad-hoc reporting and analysis

EXHIBIT B

Service Fee

(a) Service Fee: $15,000 per month rate paid in U.S. dollars by the Company to Consultant for the entire Term of this Agreement, unless otherwise agreed by the Company and Consultant in writing.

(b) Expenses: The Company will reimburse Consultant for any usual and customary business expenses as may be reasonably required to provide the services to the Company for the term of this Agreement (e.g. office supplies, travel time and mileage).

(c) Payments to Consultant: Consultant will be paid monthly on the first day of the month for services rendered the previous month (or fraction of month for first payment).

ALAUNOS THERAPEUTICS, INC. INSIDER TRADING POLICY

INTRODUCTION

During the course of your relationship with Alaunos Therapeutics, Inc. (the "***Company***"), you may receive material information that is not yet publicly available ("***material nonpublic information***") about the Company or other publicly-traded companies that the Company has business relationships with. Material nonpublic information may give you, or someone you pass that information on to, a leg up over others when deciding whether to buy, sell or otherwise transact in the Company's securities or the securities of another publicly-traded company. This policy sets forth guidelines with respect to transactions in the Company's securities by our Covered Persons (as defined below) and the other persons subject to this policy as described below, including employees, officers, directors and consultants who are advised that they are subject to this policy ("***designated consultants***").

STATEMENT OF POLICY

It is the policy of the Company that a Covered Person (or any other person subject to this policy) who is aware of material nonpublic information relating to the Company **may not**, directly or indirectly:

1. engage in any transactions in the Company's securities, except as otherwise specified under the heading "Exceptions to this Policy" below;
2. recommend the purchase or sale of any the Company's securities;
3. engage in any other action to take personal advantage of that information, including but not limited to, passing on or "tipping" that information to someone who uses it for personal gain, regardless of whether there is any personal gain by the Covered Person or the quantity of securities traded;
4. disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or
5. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies ***even if*** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of **any** material nonpublic information relating to the Company at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve

the Company's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider

alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. Tipping is illegal even if you do not personally make a trade or otherwise financially benefit from disclosing the information. For these and other reasons, it is the policy of the Company that no Covered Person (or any other person subject to this policy) may either (a) recommend to another person that they buy, hold or sell the Company's securities **at any time** or (b) disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons (unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company).

In addition, it is the policy of the Company that no Covered Person (or any other person subject to this policy) who, in the course of working for the Company, learns of or is otherwise aware of material nonpublic information about another publicly-traded company with which the Company does business or otherwise has a relationship, including a supplier, partner or collaborator of the Company, may trade in that company's securities until the information becomes public or is no longer material.

There are no exceptions to this policy, except as specifically noted above or below.

Because insider trading law is complex, you should contact the head of the Legal Department (the "Chief Legal Officer") if you have any questions about whether information in your possession is material or nonpublic or if a proposed transaction or communication would violate the insider trading laws. You must also report any unauthorized disclosure of material nonpublic information, whether inadvertent or otherwise, immediately to the Chief Legal Officer.

TRANSACTIONS SUBJECT TO THIS POLICY

This policy applies to all transactions in securities issued by the Company, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of the Company's common stock in the public market but also any other purchases, sales, transfers or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities. This policy also applies to securities of other companies about which you learn material nonpublic information during the course of your relationship with the Company.

PERSONS SUBJECT TO THIS POLICY

This policy applies to you and all other employees (permanent or temporary, salaried or hourly), officers, directors, external contractors and designated consultants of the Company and its subsidiaries (collectively, "***Covered Persons***"). This policy also applies to members of your immediate family, any other members of your family, persons with whom you share a household, persons who are your economic dependents and any other individuals or entities whose transactions in securities you or your family members influence, direct or control (including, e.g., venture or other investment funds, partnerships, corporations, trusts, and limited liability corporations). The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy.

MATERIAL NONPUBLIC INFORMATION

Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whetherthe information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- financial results or forecasts;
- status of product or product candidate development or regulatory approvals;
- clinical data relating to products or product candidates;
- the design of a clinical trial;
- timelines for pre-clinical studies or clinical trials;
- acquisitions or dispositions of assets, divisions or companies;
- public or private sales of debt or equity securities;
- stock splits, dividends or changes in dividend policy;
- the establishment of a repurchase program for the Company's securities;
- gain or loss of a significant licensor, licensee or supplier;
- changes or new corporate partner relationships or collaborations;
- notice of issuance or denial of patents;
- regulatory developments;
- management or control changes;
- names of candidates under consideration for roles in management;

- employee layoffs;
- a disruption in the Company's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- accounting restatements;
- meeting materials provided to the Board of Directors;
- litigation or settlements; and
- impending bankruptcy.

When information is considered nonpublic

The prohibition on trading when you have material nonpublic information lifts once that information becomes widely disseminated to the public, such as through a press release carried over a major news service,

a filing with the Securities and Exchange Commission (the "***SEC***"), or materials sent to stockholders (e.g., a proxy statement or a widely-disseminated prospectus). Once information is widely disseminated to the public, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered widely disseminated to the public for purposes of this policy only after two full trading days have elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then such information could be considered to no longer be nonpublic under this policy beginning on Friday; if we announce material nonpublic information after trading ends onWednesday, then such information could be considered to no longer be nonpublic under this policy beginning on Monday. Depending on the particular circumstances, the Company may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information.

The distribution of information through narrower channels, such as postings on rarely- frequented websites, may be insufficient to make it public. Also, the fact that nonpublic information is reflected in rumors in the marketplace does not mean that the information has been publicly disseminated. It is important to note that even after some information regarding a matter becomes public, many aspects relating to such matter may remain nonpublic.

QUARTERLY TRADING BLACKOUTS

Because our workplace culture tends to be open, odds are that the vast majority of Covered Persons will possess material nonpublic information at certain points during the year. To minimize even the appearance of insider trading among Covered Persons, we have established "***quarterly trading blackout periods***" during which Covered Persons and their Related Persons—regardless of whether they are aware of material nonpublic information or not—may notconduct any trades in the Company's securities. That means that, except as described in this policy, all Covered Persons and their Related Persons will be able to trade in the Company's securities only during limited open trading window periods that generally will begin after two full trading days have elapsed since the public dissemination of the Company's annual or quarterly financial results and end at the beginning of the next quarterly trading blackout period. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in the Company's securities if you are otherwise in possession of material nonpublic information.

For purposes of this policy, each quarterly trading blackout period will generally begin at the end of the day that is the last day of each fiscal quarter and end after two full trading days have elapsed since the public dissemination of the Company's financial results for that quarter. Please note that the quarterly trading blackout period may commence early or may be extended if, in the judgment of the Chief Executive Officer, President, principal accounting officer or Chief Legal Officer, there exists undisclosed information that would make trades by Covered Persons and their Related Persons inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

A Covered Person who believes that special circumstances require him or her or any of his or her Related Persons to trade during a quarterly trading blackout period should consult the Chief Legal Officer. Permission to trade during a quarterly trading blackout period will be granted only where the circumstances are extenuating, the Chief Legal Officer concludes that the person is not in fact aware of any material nonpublic information relating to the Company or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

EVENT-SPECIFIC TRADING BLACKOUTS

From time to time, an event may occur that is material to the Company and is known by only a few directors,

officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the Chief Executive Officer, President, principal accounting officer or Chief Legal Officer may not trade in the Company's securities, regardless of whether there is a quarterly trading blackout period in effect. In that situation, the Company will notify the designated individuals that neither they nor their Related Persons may trade in the Company's securities until they are informed otherwise. The existence of an event-specific trading blackout should also be considered material nonpublic information andshould not be communicated to any otherperson. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you may not trade while aware of material nonpublic information. Exceptions will not be granted during an event-specific trading blackout. The Company will notify designated individuals at the end of such event-specific trading blackout.

The quarterly and event-driven trading blackouts do not apply to those transactions to which this policy does not apply, as described under the heading "Exceptions to this Policy" below.

EXCEPTIONS TO THIS POLICY

This policy does not apply in the case of the following transactions, except as specifically noted:

1. ***Option Exercises***. This policy does not apply to the exercise of options granted under the Company's equity compensation plans for cash or, where permitted under the option, by a net exercise transaction with the Company or by delivery to the Company of already-owned Company stock. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes. This rule applies only to options or purchase rights granted by the Company. Rules pertaining to options or purchase rights granted by third parties are described in the section below captioned "Short Sales."

2. ***Tax Withholding Transactions***. This policy does not apply to the surrender of shares directly to the Company to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under the Company's equity compensation plans. However, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

2. ***10b5-1 Automatic Trading Programs***. Under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), and as permitted by the Company, Covered Persons may establish a trading plan under which a broker is instructed to buy and sell the Company's securities based on pre-determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established, purchases and sales of the Company's securities pursuant to that Trading Plan are not subject to this policy. To be properly established, a Covered Person's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of the Company at a time when they were unaware of any material nonpublic information relating to the Company and when the Company was not otherwise in a trading blackout period. Moreover, all Trading Plans must be reviewed and approved by the Company's Chief Legal Officer or his or her designee before being established to confirm that the Trading Plan complies with all pertinent company policies and applicable securities laws.

3. ***Gifts.*** This policy does not apply to *bona fide* gifts of the Company's securities that have been pre-cleared by the Company's Chief Legal Officer or his or her designee. Whether a gift is truly *bona fide* will depend on the facts and circumstances surrounding each gift. Pre-clearance must be obtained at least two business days in advance of the proposed gift, and pre-cleared gifts not completed within five

business days will require new pre-clearance. The Company may choose to shorten this period. Gifts that are designed to circumvent this policy are not permitted.

4. ***401(k) Plan***. This policy does not apply to purchases of the Company's securities in the Company's 401(k) plan resulting from your periodic contribution of money to the plan pursuant to your payroll deduction election. This policy does apply, however, to certain elections you may make under the 401(k) plan, including: (a) an election to increase or decrease the percentage of your periodic contributions that will be allocated to the Company stock fund; (b) an election to make an intra-plan transfer of an existing account balance into or out of the Company stock fund;

3. an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of your Company stock fund balance; and (d) an election to pre-pay a plan loan if the pre-payment will result in allocation of loan proceeds to the Company stock fund.

SPECIAL AND PROHIBITED TRANSACTIONS

3.1. ***Inherently Speculative Transactions.*** No Covered Person may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to the Company's stock.

3.2. ***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such

as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Covered Person to own the Company's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Covered Person may no longer have the same objectives as Company's other shareholders. Therefore, the Company's employees, directors and designated consultants are prohibited from engaging in any such transactions.

3.3. ***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in the Company's securities, Covered Persons are prohibited from holding the Company's securities in a margin account or otherwise pledging the Company's securities as collateral for a loan.

3.4. ***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructionsto a broker, and as a result the broker could execute a transaction when a Covered Person is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on the Company's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Blackouts" and "Event-Specific Trading Blackouts" provisions above.

3.5. Short Sales. You may not engage in short selling of the Company's securities. Selling short includes transactions in which you borrow securities from a broker, sell them, and eventually buy securities on the market to cover the number of securities borrowed from the broker. Profit is made if the price of the securities decreases during the period of borrowing. Short sales may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects.

PRE-CLEARANCE AND ADVANCE NOTICE OF TRANSACTIONS

In addition to the requirements above, officers, directors and other employees face a further restriction: even during an open trading window, they may not engage in any transaction in the Company's securities without first obtaining pre-clearance of the transaction from the Company's Chief Legal Officer or his or her designee at least two business days in advance of the proposed transaction. The Chief Legal Officer or his or her designee will then determine whether the transaction may proceed and, if so, will direct the Compliance Officer (as identified in the Company's Section 16 Compliance Program) to help comply with any required reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within five business days will require new pre-clearance. The Company may choose to shorten this period.

Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stockoption to the Compliance Officer or Chief Legal Officer. Once any transaction takes place, the officer, director or employee must immediately notify the Compliance Officer and any other individuals identified under the heading "Notification of Execution of Transaction" in the Company's Section 16 Compliance Program so that the Company may assist in any Section 16 reporting obligations.

SHORT-SWING TRADING, CONTROL STOCK AND SECTION 16 REPORTS

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5), which are described in the Company's Section 16 Compliance Program, and any notices of sale required by Rule 144.

POLICY'S DURATION

This policy continues to apply to your transactions in the Company's securities or the other securities covered by thispolicy even after your relationship with the Company has ended. If you are aware of material nonpublic information when your relationship with the Company ends, you may not trade the Company's securities or other covered securities until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave the Company during a trading blackout period, then you may not trade the Company's securities or the other covered securities until the trading blackout period has ended.

INDIVIDUAL RESPONSIBILITY

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in the Company's securities or other covered securities while aware of material nonpublic information. Each individual is responsible for making sure that he or she complies with thispolicy, and that any Related Person whose transactions are subject to this policy, as discussed under the heading "Persons Subject to this Policy" above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of the Company or any employee, officer or director of the Company pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and

disciplinary action by the Company for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

PENALTIES

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by the Company, including termination of employment. Anyone who has questions about this policy should contact their own attorney or the Company's Chief Legal Officer. Please also see Frequently Asked Questions, which are attached as **EXHIBIT A**.

AMENDMENTS

The Company is committed to continuously reviewing and updating its policies and procedures. The Company therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of the Company's policies regarding insider trading may be obtained by contacting the Company's legal department.

Prior Version: September 24, 2019
Approved: March 29, 2022
Effective: March 29, 2022

EXHIBIT A INSIDER TRADING POLICY FREQUENTLY ASKED QUESTIONS

1. What is insider trading?

A: Generallyspeaking, insider trading is the buying or selling of stocks, bonds, futuresor other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. Bottom line: If you are aware of material nonpublic information about the Company or another publicly-traded company that the Company has relationships with and you trade in the Company's or such other company's securities, you have broken the law.

2. Why is insider trading illegal?

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who are aware of material nonpublic information to refrain from trading.

3. What is material nonpublic information?

A: Information is material if it would influence a reasonable investor to buy or sell a stock, bond future or other security. This could mean many things: financial results, clinical or regulatory results, potential acquisitions or major contracts to name just a few. Information is nonpublic if it has not yet been publicly disseminated within the meaning of our insider trading policy.

4. Who can be guilty of insider trading?

A: Anyone who buys or sells a security while aware of material nonpublic information, or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, directors and others who don't even work at the Company. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

5. Does the Company have an insider trading policy?

A: Yes, the insider trading policy is available to read on our website at https://alaunos.com/.

6. What if I don't buy or sell anything, but I tell someone else material nonpublic information and they buy or sell?

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, both you and the "tippee"

could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the "tippee" might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about the company with anyone outside the Company, including spouses, family members, friends or business associates (unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company). This includes anonymous discussions on the internet about the Company or companies with which the Company does business.

7. What if I don't tell them theinformation itself; I justtell them whether they should buy or sell?

A: That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell the Company's common stock or any derivative security related to the Company's common stock, since that could be a form of tipping.

8. What are the sanctions if I trade on material nonpublic information or tip off someone else?

A: In addition to disciplinary action by the Company —which may include termination of employment—you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

9. What is "loss avoided"?

A: If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news. This is likely insider trading, unless an exception applies.

10. Am I restricted from trading securities of any companies other than the Company, for example a partner, collaborator or competitor of the Company?

A: Possibly. U.S. insider trading laws generally restrict everyone aware of material nonpublic information about a company from trading in that company's securities, regardless of whether the person is directly connected with that company, except in limited circumstances. Therefore, if you have material nonpublic information about another company, you should not trade in that company's securities. You should be particularly conscious of this restriction if, through your position at the Company, you sometimes obtain sensitive, material information about other companies and their business dealings with the Company.

11. So if I do not trade the Company's securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?

A: Not necessarily. Evenif you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Company stock as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

12. So when can I buy or sell the Company's securities?

A: If you are aware of material nonpublic information, you may not buy or sell our common stock until two full trading days have elapsed since all of that information was publicly disclosed. At that point, the information is considered publicly disseminated for purposes of our insider trading policy. For example, if we announce material nonpublic information before trading begins on Wednesday, then such information could be considered to no longer be nonpublic under this policy beginning on Friday; if we announce material nonpublic information after trading ends on Wednesday, then such information could be considered to no longer be nonpublic under this policy beginning on Monday. **Even if you are not aware of any material nonpublic information, you may not trade our common stock during any trading "blackout" period**. Our insider trading policy describes the quarterly trading blackout period, and additional event-specific trading blackout periods may be announced by email or otherwise.

13. If I have an open order to buy or sell the Company's securities on the date a blackout period commences, can I leave it to my broker to cancel the open order and avoid executing the trade?

A: No, unless it is in connection with a 10b5-1 trading plan (see Question 27 below). If you have any open orders when a blackout period commences other than in connection with a 10b5-1 trading plan, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after a blackout period commences not in connection with a 10b5-1 trading plan, you will have violated our insider trading policy and may also have violated insider trading laws.

14. Am I allowed to trade derivative securities of the Company's common stock?

A: No. Under our policies, you may not trade in derivative securities related to our common stock, which include publicly-traded call and put options. In addition, under our policies, you may not engage in short selling of our common stock at any time.

"Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee options and other equity awards grantedunder our equity compensation plans, which are not derivative securities for purposes of our policy.

"Short selling" is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

15. Why does the Company prohibit trading in derivative securities and short selling?

A: Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. We are dedicated to building stockholder value, short selling our common stock conflicts with our values and would not be well-received by our stockholders.

16. Can I purchase the Company's securities on margin or hold them in a margin account?

A: Under our policies, you may not purchase our common stock on margin or hold it in a margin account at any time.

"Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm.

17. Why does the Company prohibit me from purchasing the Company's securities on margin or holding them in a margin account?

A: Margin loans are subject to a margin call whether or not you possess material nonpublic information at the time of the call. If a margin call were to be made at a time when you were aware of material nonpublic information and you could not or did not supply other collateral, you may be liable under insider trading laws because of the sale of the securities (through the margin call). The sale would be attributed to you even though the lender made the ultimate determination to sell. The U.S. Securities and Exchange Commission takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.

18. Can I pledge my Company shares as collateral for a personal loan?

A: No. Pledging your shares as collateral for a personal loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

19. Can I hedge my ownership position in the Company?

A: Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own the Company's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as the Company's other shareholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.

20. Can I exercise options granted to me under the Company's equity compensation plans during a trading blackout period or when I possess material nonpublic information?

A: Yes. You may exercise the options for cash (or via net exercise transaction with the company) and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period or any time that you are aware of material nonpublicinformation. To be clear, you may not effect a broker-assisted cashless exercise (these cashless exercise transactions include a market sale) during a trading blackout period or any time that you are aware of material nonpublic information.

21. Am I subject to trading blackout periods if I am no longer an employee or consultant of the Company?

A: It depends. If your employment with the Company ends during a trading blackout period, you will be subject to the remainder of that trading blackout period. If your employment with the Company ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave the Company, you should not trade in the Company's securities if you are aware of material nonpublic information. That restriction stays with you as long as the information you possess is material and not publicly disseminated within the meaning of our insider trading policy.

22. Can I gift stock while I possess material nonpublic information or during a trading blackout period?

A: It depends. Because of the potential for the appearance of impropriety, you may only make *bona fide* gifts of our common stock when you are aware of material nonpublic information or during a trading blackout period if (and only if) the gift has been pre-cleared by the Company's Chief Legal Officer or his or her designee. Whether a gift is truly *bona fide* will depend on the facts and circumstances surrounding each gift.

23. What if I purchased publicly-traded options or other derivative securities before I became a Covered Person?

A: The same rules apply as for employee stock options. You may exercise the publicly- traded options at any time, but you may not sell the securities during a trading blackout period or at any time that you are aware of material nonpublic information.

24. May I own shares of a mutual fund that invests in the Company?

A: Yes.

25. Are mutual fund shares holding the Company common stock subject to the trading blackout periods?

A: No. You may trade in mutual funds holding the Company common stock at any time.

26. May I use a "routine trading program" or"10b5-1 plan"?

A: Subject to the requirements discussed in our insider trading policy and any 10b5-1 trading plan guidelines, eligible persons may use a routine trading program. A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stock broker where you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, please contact our legal team to confirm you are an eligible person and to obtain approval.

27. What happens if I violate our insider trading policy?

A: Violating our policies may result in disciplinary action, which may include termination of your

employment or other relationship with the Company. In addition, you may be subject to criminal and civil sanctions.

28. Who should I contact if I have questions about our insider trading policy or specific trades?

A: You should contact our Chief Legal Officer.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements Alaunos Therapeutics, Inc. (Nos. 333-129884, 333-134280, 333-142701, 333-160496, 333-167925, 333-185433, 333-199304, 333-220804, 333-228291, 333-238090, 333-241698 and 333-263983) on Form S-8 and Registration Statements (Nos. 333-134279, 333-141014, 333-162160, 333-229555, and 333-266841)) on Form S-3 of our report, dated March 31, 2025, with respect to our audit of the financial statements as of December 31, 2024 and the year then ended and of the adjustments described in Note 3 which that were applied retroactively to reflect the July 2024 one-for-ten reverse stock split in the 2023 financial statements. Our report includes an explanatory paragraph regarding the Company's ability to continue as a going concern. We also consent to reference to us under the heading "Experts" in such registration statements.

/s/ Cherry Bekaert LLP

Tampa, Florida
March 31, 2025

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, 333-241698 and 333-263983) on Form S-8 and Registration Statements (Nos. 333-134279, 333-141014, 333-162160, 333-229555, and 333-266841) on Form S-3 of Alaunos Therapeutics, Inc. of our report dated April 1, 2024, relating to the financial statements of Alaunos Therapeutics, Inc., appearing in this Annual Report on Form 10-K of Alaunos Therapeutics, Inc. for the year ended December 31, 2024.

As discussed in Note 3 to the financial statements, the 2023 financial statements have been retrospectively adjusted to apply the reverse stock split effective July 17, 2024. We have not audited the adjustments to the 2023 financial statements for this reverse stock split, as described in Note 3.

/s/ RSM US LLP

Boston, Massachusetts
March 31, 2025

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

I, Dale Curtis Hogue, Jr.., 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 31, 2025

/s/ Dale Curtis Hogue, Jr.

Dale Curtis Hogue, Jr.
Interim 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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dale Curtis Hogue, Jr.,, Interim Chief Executive Officer and Director (and 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/ Dale Curtis Hogue, Jr.
Dale Curtis Hogue, Jr.
Interim Chief Executive Officer and Director
Principal Executive Officer and
Principal Financial Officer
March 31, 2025

Exhibit 97.1

Alaunos Therapeutics, Inc.
Compensation Clawback Policy
Adopted October 3, 2023

Purpose

The Board of Directors (the "Board") of Alaunos Therapeutics, Inc. (the "Corporation") has adopted this compensation clawback policy (the "Policy") which provides for the recoupment of incentive-based compensation in the event of an accounting restatement. This Policy is intended to comply with Section 10D of the Securities Exchange Act of 1934 (the "Act"), the rules promulgated thereunder by the Securities and Exchange Commission (the "SEC"), and the listing standards of The Nasdaq Stock Market LLC ("Nasdaq" and such rules and listing standards the "Applicable Rules"), and will be interpreted consistent therewith.

Applicability and Effective Date

This Policy is effective October 2, 2023 (the "Effective Date") and is applicable to all Incentive-Based Compensation (as defined below) received by Executive Officers (as defined below) after the Effective Date. The Policy will be administered by the Board or, if so designated by the Board, the Compensation Committee of the Board (the "Committee"), in which case references to the Board will be deemed to be references to the Committee. Any determination made by the Board under this Policy will be final and binding on all affected individuals. Each Executive Officer shall be required to execute the acknowledgement in Appendix A of this Policy as soon as practicable after the later of (i) the Effective Date and (ii) the date on which the employee is designated as an Executive Officer; provided, however, that failure to execute such acknowledgement shall have no impact on the enforceability of this Policy.

Restatement Clawback

In the event the Corporation is required to prepare an Accounting Restatement (as defined below), any Executive Officer who received Excess Compensation (as defined below) during the three (3) completed fiscal years preceding the date the Corporation is required to prepare an Accounting Restatement (the "Look-Back Period") shall be required to repay or forfeit such Excess Compensation reasonably promptly. For purposes of this Policy, the date the Corporation is required to prepare an Accounting Restatement is deemed to be the earlier of the date (i) the Board concludes, or reasonably should have concluded, that the Corporation is required to prepare an Accounting Restatement, or (ii) a court, regulator, or other legally authorized body directs the Corporation to prepare an Accounting Restatement.

Method of Repayment, Conditions for Non-Recovery

The Board shall have discretion to determine the appropriate means of recovery of Excess Compensation, which may include, without limitation, direct payment in a lump sum from the Executive Officer, recovery over time, cancellation of outstanding awards, the reduction of future pay and/or awards, and/or any other method which the Board determines is advisable to achieve reasonably prompt recovery of Excess Compensation. At the direction of the Board, the Corporation shall take all actions reasonable and appropriate to recover Excess Compensation from any applicable Executive Officer, and such Executive Officer shall be required to reimburse the Corporation for any and all expenses reasonably incurred (including legal fees) by the Corporation in recovering such Excess Compensation in accordance with this Policy.

The Committee, or in the absence of the Committee, a majority of the independent directors on the Board, may determine that repayment of Excess Compensation (or a portion thereof) is not required only where it determines that recovery would be impracticable and one of the following circumstances exists: (i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered, provided the Corporation has (A) made a reasonable attempt to recover such Excess Compensation, (B) documented such reasonable attempt, and (C) provided such documentation to Nasdaq; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Corporation, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

No Fault Application, No Indemnification

Recovery of Excess Compensation under this Policy is on a "no fault" basis, meaning that it will occur regardless of whether the Executive Officer engaged in misconduct or was otherwise directly or indirectly responsible, in whole or in part, for the Accounting Restatement. No Executive Officer may be indemnified by the Corporation, or any of its affiliates, from losses arising from the application of this Policy.

Definitions

For purposes of this Policy, the following definitions will apply:

"Accounting Restatement" means an accounting restatement due to the material noncompliance of the Corporation with any financial reporting requirement under securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that corrects an error that is not material to previously issued financial statements but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

Changes to financial statements that do not constitute an Accounting Restatement include retroactive: (i) application of a change from one generally accepted accounting principle to another generally accepted accounting principle; (ii) revisions to reportable segment information due to a change in internal organization; (iii) reclassification due to a discontinued operation; (iv) application of a change in reporting entity, such as from a reorganization of entities under common control; and (v) revisions for stock splits, reverse stock splits, stock dividends, or other changes in capital structure.

"Excess Compensation" means any amount of Incentive-Based Compensation received by an Executive Officer after commencement of service as an Executive Officer that exceeds the amount of Incentive-Based Compensation that otherwise would have been received had it been determined based on the Accounting Restatement, computed without regard to any taxes paid. For Incentive Compensation based on stock price or total shareholder return, where the amount to be recovered is not subject to mathematical recalculation directly from information in the Accounting Restatement, the amount to be recovered shall be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return, as applicable, and the Corporation shall retain documentation of the determination of such estimate and provide such documentation to Nasdaq if so required by the Applicable Rules. Incentive-Based Compensation is deemed received during the fiscal year during which the applicable financial reporting measure, stock price and/or total shareholder return measure, upon which the payment is based, is achieved, even if the grant or payment occurs after the end of such period.

"Executive Officer" means an individual who is, or was during the Look-Back Period, an executive officer of the Corporation within the meaning of Rule 10D-1(d) under the Act.

"Incentive-Based Compensation" means any compensation that is granted, earned or vested based wholly or in part on stock price, total shareholder return, and/or the attainment of (i) any financial reporting measure(s) that are determined and presented in accordance with the accounting principles used in preparing the Corporation's financial statements and/or (ii) any other measures that are derived in whole or in part from such measures.

Compensation that does not constitute "Incentive-Based Compensation" includes equity incentive awards for which the grant is not contingent upon achieving any financial reporting measure performance goal for an individual to receive such award and that vest exclusively upon completion of a specified employment period, without any performance condition, and bonus awards that are discretionary or based on subjective goals or goals unrelated to financial reporting measures.

Administration, Amendment, and Termination

This Policy will be enforced and, if applicable, appropriate proxy disclosures and exhibit filings will be made in accordance with the Applicable Rules and any other applicable rules and regulations of the SEC.

The Board shall have authority to (i) exercise all of the powers granted to it under the policy, (ii) construe, interpret, and implement this Policy, and (iii) make all determinations necessary or advisable in administering this Policy.

In addition, the Board may amend this Policy, from time to time in its discretion, and shall amend this Policy, as it deems necessary, including to reflect changes in applicable law, rule or regulation. The Board may terminate this Policy at any time. Any such amendment (or provision thereof) or termination shall not be effective if such amendment or termination would (after taking into account any actions taken by the Corporation contemporaneously with such amendment or termination) cause the Corporation to violate the Applicable Rules.

In the event of any conflict or inconsistency between this Policy and any other policies, plans, or other materials of the Corporation (including any agreement between the Corporation and any Executive Officer subject to this Policy), this Policy will govern.

This Policy will be deemed to be automatically updated to incorporate any requirement of law, rule or regulation applicable to the Corporation, including those promulgated by the SEC and the Applicable Rules.

Appendix A:

Alaunos Therapeutics, Inc.
Compensation Clawback Policy

ACKNOWLEDGMENT

The undersigned acknowledges and agrees that the undersigned (i) is, and will be, subject to the Compensation Clawback Policy to which this acknowledgement is appended, as may be amended from time to time (the "Policy") and (ii) will abide by the terms of the Policy, including by returning Excess Compensation pursuant to whatever method the Board determines is advisable to achieve reasonably prompt recovery of such Excess Compensation, as prescribed under the Policy.

Capitalized terms used but not defined have the meanings set forth in the Policy.

_____
Print Name

_____
Signature

Dated: