
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

Form 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2024

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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

(I.R.S. Employer
Identification No.)

2617 Bissonnet Street, Suite 225
Houston, TX 77005
(346) 355-4099

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

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 preceding 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, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company and emerging growth company in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	<input checked="" type="checkbox"/>	Smaller Reporting Company	<input checked="" type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 14, 2024, the number of outstanding shares of the registrant's common stock, \$0.001 par value, was 1,601,252 shares.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly 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 Quarterly 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 Quarterly 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 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 Quarterly Report on Form 10-Q 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 to differ materially from current expectations include, among other things, those described under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. 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 Quarterly 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®, Ziopharm® and hunTR® as well as the graphic trademark found on our website. Other trademarks, service marks and trade names appearing in this Quarterly Report are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Quarterly Report 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 II, Item 1A of this Quarterly 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 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.
- Due to our continued monitoring by Nasdaq for compliance with the Minimum Bid Price Rule until 2025, we could at any time during which we could be delisted again if we again fail to comply with the Minimum Bid Price Rule. 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.
- 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 during the monitor period.
- Even if we do get approval and effectuate a third reverse stock split, the trading price of our common stock may not meet the Minimum Bid Price Rule.
- In light of the recent reverse stock splits, or if we implement a third reverse stock split during the monitor period, liquidity of our common stock may be materially and adversely affected.
- 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.
- We may identify material weaknesses in the future or otherwise fail to maintain an effective internal controls system, which may result in material misstatements of our financial statements or have a material adverse effect on our business or stock price.
- The termination of our licenses and research and development agreement with the National Cancer Institute and Precigen could limit our ability to resume our clinical trial or begin new clinical trials focused on TCR-T.
- The termination of our licenses with Precigen or MD Anderson with respect to *Sleeping Beauty* and mbIL-15 or our research and development agreements with MD Anderson could result in the loss of significant rights and could materially harm our ability to develop and commercialize our product candidates by limiting our ability to resume our clinical trial or begin new clinical trials focused on TCR-T.
- 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.
- For our small molecule oral obesity program or should we resume development of our product candidates of our TCR-T program, we may not be able to commercialize them, generate significant revenues, or attain profitability.
- Our small molecule obesity program is very early stage and may encounter issues with manufacture of the active pharmaceutical ingredient or with the in vitro or in vivo validation studies that could preclude clinical trials or be costly to address with respect to time or money.
- We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

- 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.
- 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 of our TCR-T program or for our small molecule oral obesity program.
- We have halted development of our TCR-T product candidates 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. We cannot be certain if or when we will be able to submit a Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or the FDA, and the delay, or any failure, in completing clinical trials for our product candidates could significantly harm our business.
- 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 our *Sleeping Beauty* system used to manufacture our product candidates may incorrectly modify the genetic material of a patient's T cells, potentially triggering the development of a new cancer or other adverse events.
- For our small molecule oral obesity program or should we resume development of our product candidates of our TCR-T program, 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 product candidates of our TCR-T program, our inability to obtain the necessary U.S. or worldwide regulatory approvals to commercialize any product candidate, our business will suffer materially.
- 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, our ability to generate revenue from sales of our products will be materially and adversely impaired.
- Our ability to generate product revenues will be diminished if our products do not obtain coverage and adequate reimbursement from payors.
- The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.
- Our immuno-oncology product candidates may face competition in the future from 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.
- 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.
- We relied and, for our small molecule oral obesity program or 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 harm our ability to operate our business effectively and materially and adversely affect our business and reputation.
- Our stock price has been, and may continue to be, volatile.
- 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.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

Alaunos Therapeutics, Inc.
CONDENSED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share data)

	September 30, 2024	December 31, 2023
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 1,683	\$ 6,062
Receivables	—	1
Prepaid expenses and other current assets	1,867	2,198
Total current assets	3,550	8,261
Property and equipment, net	—	2
Total assets	<u>\$ 3,550</u>	<u>\$ 8,263</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 458	\$ 616
Accrued expenses	368	1,340
Total current liabilities	826	1,956
Total liabilities	<u>\$ 826</u>	<u>\$ 1,956</u>
Commitments and contingencies		
Stockholders' equity		
Common stock \$0.001 par value; 5,000,000 shares authorized, 1,601,252 shares issued and outstanding at September 30, 2024 and at December 31, 2023	2	2
Additional paid-in capital	922,426	922,072
Accumulated deficit	(919,704)	(915,767)
Total stockholders' equity	2,724	6,307
Total liabilities and stockholders' equity	<u>\$ 3,550</u>	<u>\$ 8,263</u>

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

Alaunos Therapeutics, Inc.
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	\$ —	\$ —	\$ 6	\$ 4
Operating expenses:				
Research and development	143	3,656	448	15,346
General and administrative	1,007	3,578	3,615	9,791
Gain on lease modification	—	—	—	(245)
Restructuring costs	—	419	—	419
Property and equipment and right-of-use asset impairment	—	1,011	—	1,011
Total operating expenses	1,150	8,664	4,063	26,322
Loss from operations	(1,150)	(8,664)	(4,057)	(26,318)
Other income (expense):				
Interest expense	—	—	—	(1,921)
Other income, net	23	188	120	942
Other income (expense), net	23	188	120	(979)
Net loss	\$ (1,127)	\$ (8,476)	\$ (3,937)	\$ (27,297)
Basic and diluted net loss per share	<u>\$ (0.70)</u>	<u>\$ (5.30)</u>	<u>\$ (2.46)</u>	<u>\$ (17.07)</u>
Weighted average common shares outstanding, basic and diluted	<u>1,601,252</u>	<u>1,600,306</u>	<u>1,601,252</u>	<u>1,598,948</u>

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

Alaunos Therapeutics, Inc.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share and per share data)

For the Three Months Ended September 30, 2024

	Common Stock		Additional Paid in Capital		Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2024	1,601,252	2	\$ 922,346	\$ (918,577)	\$ 3,771	
Stock-based compensation	—	—	80	—	—	80
Net loss	—	—	—	(1,127)	(1,127)	(1,127)
Balance at September 30, 2024	<u>1,601,252</u>	<u>\$ 2</u>	<u>\$ 922,426</u>	<u>\$ (919,704)</u>	<u>\$ 2,724</u>	

For the Nine Months Ended September 30, 2024

	Common Stock		Additional Paid in Capital		Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2024	1,601,252	\$ 2	\$ 922,072	\$ (915,767)	\$ 6,307	
Stock-based compensation	—	—	354	—	—	354
Net loss	—	—	—	(3,937)	(3,937)	(3,937)
Balance at September 30, 2024	<u>1,601,252</u>	<u>\$ 2</u>	<u>\$ 922,426</u>	<u>\$ (919,704)</u>	<u>\$ 2,724</u>	

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

Alaunos Therapeutics, Inc.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share and per share data)

For the Three Months Ended September 30, 2023

	Common Stock		Additional Paid in Capital		Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2023	1,604,180	\$ 2	\$ 921,096	\$ (899,448)	\$ 21,650	
Stock-based compensation	—	—	726	—	—	726
Net loss	—	—	—	(8,476)	(8,476)	
Balance at September 30, 2023	1,604,180	\$ 2	\$ 921,822	\$ (907,924)	\$ 13,900	

For the Nine Months Ended September 30, 2023

	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	—	—	2,550	—	—	2,550
Issuance of common stock, net of expenses	1,442	—	92	—	—	92
Net loss	—	—	—	(27,297)	(27,297)	
Balance at September 30, 2023	1,604,180	\$ 2	\$ 921,822	\$ (907,924)	\$ 13,900	

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

Alaunos Therapeutics, Inc.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	For the Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (3,937)	\$ (27,297)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3	2,074
Property and equipment right-of-use asset impairment	—	1,011
Amortization of financing costs	—	1,339
Stock-based compensation	354	2,550
Decrease in the carrying amount of right-of-use assets	—	1,332
Gain on lease modification	—	(245)
Loss on disposal of equipment	—	12
Changes in operating assets and liabilities:		
Receivables	1	4
Prepaid expenses and other current assets	331	(126)
Deposits	—	42
Accounts payable	(159)	(92)
Accrued expenses	(972)	(2,258)
Lease liabilities	—	(1,575)
Other liabilities, non-current	—	472
Net cash used in operating activities	(4,379)	(22,757)
Cash flows from investing activities:		
Purchases of property and equipment	—	(197)
Proceeds from the disposal of property and equipment	—	40
Net cash used in investing activities	—	(157)
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	(4,379)	(41,052)
Cash, cash equivalents and restricted cash, beginning of period	6,062	52,996
Cash and cash equivalents, end of period	<u>\$ 1,683</u>	<u>\$ 11,944</u>
Supplementary disclosure of cash flow information:		
Cash paid for interest	<u>\$ —</u>	<u>\$ 2,063</u>

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

Alaunos Therapeutics, Inc.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

1. Organization

Overview

Alaunos Therapeutics, Inc., which is referred to herein as "Alaunos," or the "Company," is a pre-clinical-stage cell therapy and obesity therapy-focused company that 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 leveraged its proprietary, non-viral *Sleeping Beauty* gene transfer platform and its novel cancer mutation hotspot TCR library to design and manufacture personalized cell therapies that target neoantigens arising from common tumor-related mutations in key oncogenic genes, including *KRAS*, *TP53* and *EGFR*. The Company recently announced that it is currently evaluating its internally developed small molecule oral obesity treatment program. The Company plans to develop a drug for obesity with a differentiated profile relative to currently marketed and in development oral and injectable products. The Company believes the small molecule product candidates are distinct from commercially available options or others in development because they do not rely on hormonal manipulation, which is common with many obesity treatments.

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

As of September 30, 2024, there were 1,601,252 shares of common stock outstanding and an additional 59,792 shares of common stock reserved for issuance pursuant to outstanding stock options and warrants.

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 has significantly reduced its workforce and continues working to reduce costs in order to extend its cash runway. 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 engaged Cantor Fitzgerald & Co., or Cantor, to act as strategic advisor for this process. Separately, the Company is evaluating several potential opportunities including evaluating its own internal obesity program.

The accompanying condensed 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 September 30, 2024, the Company had approximately \$1.7 million of cash and cash equivalents. The Company's accumulated deficit at September 30, 2024 was approximately \$919.7 million. Given its current development plans and cash management efforts, the Company anticipates cash resources will be sufficient to fund operations into the first quarter of 2025. The Company's ability to continue operations after its current cash resources are exhausted depends on future events outside of the Company's control, including its ability to obtain additional financing or to achieve profitable results, as to which no assurances can be given. 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 condensed financial statements, and substantial doubt as to the Company's ability to continue as a going concern exists. This forecast of cash resources is forward-looking information that involves risks and uncertainties, and the actual amount of expenses could vary materially and adversely as a result of a number of factors.

Basis of Presentation

The accompanying unaudited interim condensed financial statements reflect all adjustments (which are normal and recurring) that are necessary for a fair presentation of the financial position of the Company and its results of operations and cash flows for the periods presented. The unaudited interim condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2023, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024, or the Annual Report.

The results disclosed in the statements of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for the full fiscal year 2024.

Alaunos Therapeutics, Inc.

**NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)**

Use of Estimates

The preparation of condensed financial statements in conformity with 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 condensed financial statements and the reported amounts of revenues 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.

Reverse Stock Splits

On January 31, 2024, the Company filed a Second Amended and Restated Certificate of Incorporation or (the Second 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 or the Reverse Split. The Second Charter Amendment decreased the number of authorized shares of common stock from 520,000,000 to 34,666,667. The Second 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 Second 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 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 it had occurred at the beginning of the earliest period presented.

2. Financings

2022 Equity Distribution Agreement

On August 12, 2022, the Company entered into an Equity Distribution Agreement, or the Equity Distribution Agreement, with Piper Sandler & Co., or Piper Sandler, pursuant to which the Company can offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to \$50.0 million through Piper Sandler as its sales agent in an "at the market offering." Piper Sandler will receive a commission of 3.0% of the gross proceeds of any common stock sold under the Equity Distribution Agreement. During the three and nine months ended September 30, 2024 and 2023, there were no sales of the Company's common stock under the Equity Distribution Agreement.

3. Summary of Significant Accounting Policies

The Company's significant accounting policies were identified in the Company's Annual Report. There have been no material changes in those policies since the filing of its Annual Report.

4. Net loss per share

Basic net loss per share of common stock 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

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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. Such potentially dilutive shares of common stock consisted of the following as of September 30, 2024 and 2023:

	September 30,	
	2024	2023
Common stock options	33,237	82,780
Unvested restricted stock	-	2,916
Warrants	26,555	152,815
	<hr/>	<hr/>
	59,792	238,511

5. Related Party Transactions

Joint Venture regarding Eden BioCell

On December 18, 2018, the Company launched Eden BioCell, Ltd., or Eden BioCell, as a 50/50 joint venture with a company affiliated with the Chair of the Company's board of directors at that time, or Partner. Eden BioCell was formed 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. The Partner contributed \$10.0 million to Eden BioCell and has committed up to an additional \$25.0 million to this joint venture. The Partner also managed all clinical development in the territory pursuant to a master services agreement between with Eden BioCell.

In September 2021, the Partner and Alaunos mutually agreed to dissolve the Eden BioCell joint venture. The joint venture agreement has been terminated and 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 three and nine months ended September 30, 2023, the Company recorded expenses of approximately \$12 and \$37, respectively, for consulting services performed by Dune Lake Capital. The Company did not incur expenses to Dune Lake Capital during the three and nine months ended September 30, 2024.

6. Commitments and Contingencies

License Agreements

Exclusive License Agreement with Precigen

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. The Company further maintained its 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 remained 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 were no longer exclusively licensed to the Company. The Company was no longer obligated to use commercially reasonable efforts for the exclusively licensed products. The A&R License Agreement further eliminated 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 was no longer obligated to pay the Company royalties on the net sales derived from the sale of Precigen's CAR products. 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.

See Note 8. Subsequent Events for details related to the termination of the A&R License Agreement with Precigen.

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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. The activities under the 2015 R&D Agreement are directed by a joint steering committee comprised of two members from the Company and one member from MD Anderson.

As provided under the MD Anderson License, the Company provided funding for research and development activities in support of the research programs under the 2015 R&D Agreement for a period of three years and in an amount of no less than \$15.0 million and no greater than \$20.0 million per year. On November 14, 2017, the Company entered into an amendment to the 2015 R&D Agreement, extending its term until April 15, 2021. In connection with the execution of the 2019 R&D Agreement described below, on October 22, 2019, the Company amended the 2015 R&D Agreement to extend the term of the 2015 R&D Agreement until December 31, 2026 and to allow cash resources on hand at MD Anderson under the 2015 R&D Agreement to be used for development costs under the 2019 Research and Development Agreement, or the 2019 R&D Agreement, which 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. The Company did not incur clinical costs from MD Anderson related to the 2015 R&D Agreement for the three and nine months ended September 30, 2024.

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

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

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

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

Under the 2019 R&D Agreement, the Company agreed, beginning on January 1, 2021, to reimburse MD Anderson up to a total of \$20.0 million for development costs under the 2019 R&D Agreement, after the funds from the 2015 R&D Agreement are exhausted. In addition, the Company will pay MD Anderson royalties on net sales of its TCR products. The Company is required to make performance-based payments upon the successful completion of clinical and regulatory benchmarks relating to its TCR products. The aggregate potential benchmark payments are \$36.5 million, of which only \$3.0 million will be due prior to the first marketing approval of the Company's TCR products. The royalty rates and benchmark payments owed to MD Anderson may be reduced upon the occurrence of certain events. The Company also agreed to sell its TCR products to MD Anderson at preferential prices and will sell the Company's

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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 three and nine months ended September 30, 2024 the Company did not incur clinical expenses from MD Anderson related to the 2019 R&D Agreement, compared to \$0.2 and \$0.7 million for the three and nine months ended September 30, 2023.

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 September 30, 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.

For the three and nine months ended September 30, 2024, the Company did not incur expenses to the NCI under this agreement, compared to \$0.01 and \$0.5 million for the three and nine months ended September 30, 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.

On August 14, 2023, the Company announced that it had provided the requisite notice to terminate the CRADA, pursuant to its terms, effective October 13, 2023, in light of the Company's exploration of strategic alternatives.

The Company did not record expenses under the CRADA for the three and nine months ended September 30, 2024, compared to \$0.00 and \$0.5 million for the three and nine months ended September 30, 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

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the Company may receive from a possible sublicense under certain circumstances. During the three and nine months ended September 30, 2024 and 2023, the Company did not incur any milestone expenses or royalty expenses on sales under this agreement.

Collaboration Agreement with Solasia Pharma K.K.

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

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

In June 2022, Solasia announced that darinaparsin had been approved from relapsed or refractory Peripheral T-Cell Lymphoma by the Ministry of Health, Labor and Welfare in Japan. During the three months ended September 30, 2024 and 2023, the Company did not earn collaboration revenue and did not earn royalty revenues on net sales under the Solasia License and Collaboration Agreement. During the nine months ended September 30, 2024 and 2023, the Company earned collaboration revenue of \$0 and \$0 and earned royalty revenues of \$6 thousand and \$4, respectively, of 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.

7. Stock-Based Compensation

The Company recognized stock-based compensation expense on all employee and non-employee awards as follows:

<i>(in thousands)</i>	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 2	\$ 90	\$ 15	\$ 446
General and administrative	78	636	339	2,104
Stock-based compensation expense	<u>\$ 80</u>	<u>\$ 726</u>	<u>\$ 354</u>	<u>\$ 2,550</u>

The Company granted an aggregate of 3,000 stock options during the three months ended September 30, 2024, with a weighted-average grant date fair value of \$2.06 per share, and granted an aggregate of 66 stock options during the three months ended September 30, 2023, with a weighted-average grant date fair value of \$58.5 per share. The Company granted an aggregate of 13,289 stock options during the nine months ended September 30, 2024, with a weighted-average grant date fair value of \$10.84 per share, and granted an aggregate of 24,634 stock options during the nine months ended September 30, 2023, with a weighted-average grant date fair value of \$58.5 per share.

For the three and nine months ended September 30, 2024 and 2023, the fair value of stock options was estimated on the date of grant using a Black-Scholes option valuation model with the following assumptions:

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	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Risk-free interest rate	3.70%	4.01	3.70 – 4.09%	3.51 – 4.01%
Expected life in years	6.06	6.25	5.04-6.06	5.06 – 6.25
Expected volatility	112.17%	90.65	112.17 -170.5	89.69 – 95.63%
Expected dividend yield	—%	—%	—%	—%

Stock option activity under the Company's stock option plans for the nine months ended September 30, 2024 was as follows:

<i>(in thousands, except share and per share data)</i>	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2023	46,589	\$ 268.50	7.64	\$ —
Granted	13,289	10.84		
Exercised	-	-		
Cancelled	(26,641)	283.08		
Outstanding, September 30, 2024	33,237	\$ 153.79	7.45	\$ —
Options exercisable, September 30, 2024	<u>20,729</u>	<u>\$ 250.45</u>	<u>6.35</u>	<u>\$ —</u>
Options available for future grant, September 30, 2024	<u>142,745</u>			

At September 30, 2024, total unrecognized compensation costs related to unvested stock options outstanding amounted to \$0.4 million. The cost is expected to be recognized over a weighted-average period of 1.34 years.

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8. Subsequent Events

Termination of Material Definitive Agreement

As previously disclosed, on April 3, 2023, the Company entered into the A&R License Agreement with Precigen, which A&R License Agreement amended and restated in entirety the parties' previous license agreement, dated October 5, 2018, by and among the same parties, for the grant of certain licenses by Precigen to the Company to develop *Sleeping Beauty*-transposed neoantigen T-cell receptors for the treatment of solid tumor cancers. On October 4, 2024, the Company provided written notice to Precigen to terminate the A&R License Agreement.

The decision to not renew the A&R License Agreement was made after a thorough review of our strategic priorities and business objectives, including recognizing that the non-viral *Sleeping Beauty* gene transfer platform patent will expire in 2026. The Company continues to prosecute certain of the intellectual property underlying the TCRs targeting driver mutations such as KRAS, TP53 and EGFR, and the hunTR TCR discovery platform used in the discovery of our proprietary TCR library. 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.

Item 2. 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 unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial information and related notes included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission, or the SEC, on April 1, 2024, or the Annual Report.

Except for the historical financial information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to contain forward-looking statements that reflect our plans, estimates and beliefs. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as "aim", "may," "expect," "anticipate," "estimate," "intend," "plan" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results could differ materially from those contained in or implied by any forward-looking statements. Factors that could cause or contribute to these differences include those risks identified under Part II, Item 1A. Risk Factors.

All share amounts presented in this Item 2 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

We have 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. We were working to leverage our cancer hotspot mutation TCR library and our proprietary, non-viral *Sleeping Beauty* gene transfer platform to design and manufacture patient-specific cell therapies that target neoantigens arising from shared tumor-specific mutations in key oncogenic genes, including *KRAS*, *TP53* and *EGFR*. In collaboration with the MD Anderson Cancer Center, or MD Anderson, we were enrolling and treating patients for a Phase 1/2 clinical trial which was 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.

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 significantly 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 have engaged Cantor Fitzgerald & Co., or Cantor, to act as strategic advisor for this process. In addition, on August 14, 2023, we announced that we had provided the requisite notice to the NCI to terminate the Cooperative Research and Development Agreement, dated January 9, 2017, by and among us, the National Cancer Institute, or the NCI, and Intrexon Corporation, or Intrexon, as amended (such agreement referred to herein as the CRADA), pursuant to its terms, effective October 13, 2023. In addition, on October 27, 2023, we provided notice of termination of the Patent License with the NCI, effective December 26, 2023. Further, on October 4, 2024, we terminated the A&R License Agreement with Precigen.

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 not generated any product revenue and have incurred significant net losses in each year since our inception. For the nine months ended September 30, 2024, we had a net loss of \$3.9 million, and as of September 30, 2024, we have incurred approximately \$919.7 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.

Recent Developments

TCR-T Library Phase 1/2 Trial

Eight patients were treated and evaluated in our TCR-T Library Phase 1/2 Trial. 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. Disease control was measured by objective responses and stable disease. Increased secretion of interferon-gamma relative to baseline was detected in all patients' serum post-cell transfer suggesting recognition of the tumor by the infused TCR-T cells. Persistence of TCR-T cells in peripheral blood was detected in all evaluable patients at their last follow-up, including up to six months in one patient. Infiltration of TCR-T cells into the tumor was also detected in three samples where a fresh biopsy was collected suggesting homing to the tumor microenvironment. All patients have progressed or withdrawn from the trial and long-term follow-up is ongoing for a subset of patients with no further intervention per the treatment protocol. 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. In connection with the strategic reprioritization, we have reduced our workforce by approximately 95% to date in order to streamline the organization and to maximize our cash runway.

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 will be subject to a mandatory panel monitor for the one-year period through February 16, 2025.

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 a drug for obesity 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 have engaged a contract development and manufacturing organization (CMDO) to manufacture active pharmaceutical ingredients for our small molecule product candidates. We believe reductions in overhead expenditures have extended the Company's cash runway into the first quarter of 2025. We anticipate initiating *in vitro* testing of our candidates in the fourth quarter 2024. If successful, we plan to conduct an *in vivo* efficacy study in the first half of 2025, followed by the initiation of nonclinical and IND-enabling activities in 2025. Our ability to execute on this plan is dependent on study results and our ability to raise additional capital or obtain a development partner in connection with the development of these assets.

Financial Overview

Revenue

We recognize royalties, 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 U.S. Food and Drug Administration, or 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 and sponsored research fees paid to third parties.

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.

Other Income (Expense)

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

Results of Operations

Three and Nine Months Ended September 30, 2024 Compared to Three and Nine Months Ended September 30, 2023

Revenue

Revenue during the three and nine months ended September 30, 2024 and 2023 was as follows:

(\$ in thousands)	Three Months Ended September 30, 2024		Change	Nine Months Ended September 30, 2024		Change		
	2024	2023		2024	2023			
Revenue	\$ —	\$ —	\$ —	100 %	\$ 6	\$ 4	\$ 2	50 %

The company did not earn revenue during the three months ended September 30, 2024 and 2023. Revenue during the nine months ended September 30, 2024 was \$6 thousand and was \$4 thousand for the nine months ended September 30, 2023.

Research and Development Expenses

Research and development expenses during the three and nine months ended September 30, 2024 and 2023 were as follows:

(\$ in thousands)	Three Months Ended September 30, 2024		Change	Nine Months Ended September 30, 2024		Change		
	2024	2023		2024	2023			
Research and development expenses	\$ 143	\$ 3,656	\$ (3,513)	(96)%	\$ 448	\$ 15,346	\$ (14,898)	(97)%

Research and development expenses for the three months ended September 30, 2024 decreased by \$3.5 million when compared to the three months ended September 30, 2023, primarily due to lower program expenses of \$1.7 million as a result of the wind-down of our clinical activities, a \$1.1 million decrease in consulting and employee-related expenses due to our reduced headcount and a \$0.7 million decrease in facility related cost due to the wind-down.

Research and development expenses for the nine months ended September 30, 2024 decreased by \$14.8 million when compared to the nine months ended September 30, 2023, primarily due to lower program expenses of \$7.9 million as a result of the wind-down of our clinical activities, a \$4.6 million decrease in consulting and employee-related expenses due to our reduced headcount and a \$2.4 million decrease in facility related cost due to the wind-down.

For the three and nine months ended September 30, 2024, 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 currently in the process of winding down.

General and Administrative Expenses

General and administrative expenses during the three and nine months ended September 30, 2024 and 2023 were as follows:

(\$ in thousands)	Three Months Ended September 30, 2024		Change	Nine Months Ended September 30, 2024		Change		
	2024	2023		2024	2023			
General and administrative expenses	\$ 1,007	\$ 3,578	\$ (2,571)	(72)%	\$ 3,615	\$ 9,791	\$ (6,176)	(63)%

General and administrative expenses for the three months ended September 30, 2024 decreased by \$2.6 million as compared to the three months ended September 30, 2023, primarily due to a \$2.4 million decrease in consulting and employee-related expenses due to our reduced headcount, and a \$0.1 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.

General and administrative expenses for the nine months ended September 30, 2024 decreased by \$6.2 million as compared to the nine months ended September 30, 2023, primarily due to a \$3.2 million decrease in employee-related expenses due to our reduced headcount, a \$2.5 million decrease in consulting expenses and a \$0.4 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.

Other Income (Expense)

Other income (expense) during the three and nine months ended September 30, 2024 and 2023 was as follows:

(\$ in thousands)	Three Months Ended September 30,			Nine Months Ended September 30,			Change
	2024	2023	Change	2024	2023	Change	
	\$ —	\$ —	\$ —	\$ —	\$ (1,921)	\$ 1,921	(100)%
Interest expense	\$ —	\$ —	\$ —	\$ —	\$ (1,921)	\$ 1,921	(100)%
Other income, net	\$ 23	\$ 188	(165)	(88)%	120	942	(87)%
Total	\$ 23	\$ 188	\$ (165)	(88)%	\$ 120	\$ (979)	\$ 1,099
							(112)%

Other income (expense), net, for the three months ended September 30, 2024 decreased by \$0.2 million as compared to the three months ended September 30, 2023.

Other income (expense), net, for the nine months ended September 30, 2024 increased by \$1.1 million as compared to the nine months ended September 30, 2023, primarily due to no interest expense associated with our former amended Loan and Security Agreement (as defined below).

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 equity securities, term debt and collaborations. Through December 31, 2023, we have received an aggregate of \$729.2 million from issuances of equity. We have had no financing activity for the nine months ended September 30, 2024.

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 have 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 condensed 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 third quarter of 2024. 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 condensed 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 decrease in cash and cash equivalents for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30, 2024		2023	
(\$ in thousands)				
Net cash used in:				
Operating activities	\$	(4,379)	\$	(22,757)
Investing activities		—		(157)
Financing activities		—		(18,138)
Net decrease in cash and cash equivalents	\$	<u>(4,379)</u>	\$	<u>(41,052)</u>

Net cash used in operating activities for the nine months ended September 30, 2024 was \$4.4 million, as compared to net cash used in operating activities of \$22.8 million for the nine months ended September 30, 2023. The decrease in net cash used in operation activities was primarily related to changes in our net loss.

The net cash used in operating activities for the nine months ended September 30, 2024 was primarily due to our net loss of \$3.9 million, adjusted for \$0.4 million of non-cash items such as depreciation and stock-based compensation and a \$0.9 million decrease in accrued expenses, a decrease in accounts payable of \$0.2 million, a decrease to prepaid expenses and other current assets and accounts receivables of \$0.3 million.

Net cash used in investing activities was \$0 for the nine months ended September 30, 2024, compared to \$0.2 million for the nine months ended September 30, 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 for the nine months ended September 30, 2024 was \$0, compared to \$18.1 million for the nine months ended September 30, 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 September 30, 2024, our accumulated deficit was approximately \$919.7 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.

As of September 30, 2024, we had approximately \$1.7 million of cash and cash equivalents. In light of our announced strategic reprioritization and concurrent exploration of strategic alternatives, including our decision to halt work on our TCR-T Library Phase 1/2 Trial, our development programs and reducing our workforce, we anticipate our cash resources will be sufficient to fund our operations into the third quarter of 2024. 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.

Working capital as of September 30, 2024 was \$2.8 million, consisting of \$3.6 million in current assets and \$0.8 million in current liabilities. Working capital as of December 31, 2023 was \$6.3 million, consisting of \$8.3 million in current assets and \$2.0 million in current liabilities.

Royalty and License Fees

On May 28, 2019, we entered into a patent license agreement, or the Patent License, with the NCI. The terms of the Patent License required us to pay the NCI minimum annual royalties in the amount of \$0.3 million, which would be reduced to \$0.1 million once the aggregate minimum annual royalties paid by us equaled \$1.5 million. For the three and nine months ended September 30, 2024, we did not recognize royalty payments under the Patent License, and for the three and nine months ended September 30, 2023, we recognized \$0.0 and \$0.3 million related to royalty payments under the Patent License. As of September 30, 2024, we paid a total of \$0.8 million in minimum annual royalty payments under the Patent License. On October 27, 2023, we provided notice of termination of the Patent License with the NCI, effective December 26, 2023.

On October 5, 2018, we entered into the License Agreement with PGEN Therapeutics, Inc., or PGEN, a wholly owned subsidiary of Precigen. Except where the context otherwise requires, we refer to PGEN and Precigen together as Precigen.

Pursuant to the A&R License Agreement, annual license payments due to Precigen are \$75 thousand. Payment of the licensing fee is scheduled annually, in the second quarter after the first payment in October 2023; therefore, in accordance with the terms of the agreement, no amounts were paid during the three and nine months ended September 30, 2024 or 2023. On October 4, 2024, the Company provided written notice to Precigen to terminate the A&R License Agreement.

In June 2022, Solasia Pharma K. K., or Solasia, announced that darinaparsin had been approved for relapsed or refractory Peripheral T-Cell Lymphoma by the Ministry of Health, Labor and Welfare in Japan. During the three months ended September 30, 2024 and 2023, the Company did not earn collaboration revenue and did not earn royalty revenues on net sales under the Solasia License and Collaboration Agreement. During the nine months ended September 30, 2024 and 2023, we recorded revenue of \$6 thousand and \$4 thousand under the License and Collaboration Agreement, respectively.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

As a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, we are not required to provide the information under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal accounting officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) as of September 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our principal executive officer and principal accounting officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13(a)-15(f) of the Exchange Act) that occurred during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. 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 from time to time. 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 an adverse impact on us because of defense costs, diversion of management attention and 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 1A. Risk Factors

The following important factors could cause our actual business and financial results to differ materially from those contained in forward-looking statements made in this Quarterly Report on Form 10-Q or elsewhere by management from time to time. The risk factors in this Quarterly Report have been revised to incorporate changes to our risk factors from those included in our Annual Report. The risk factors set forth below with an asterisk (*) before the title are new risk factors or ones containing substantive changes from the risk factors previously disclosed in Item 1A of our Annual Report, as filed with the SEC. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of your investment. This situation is changing rapidly and additional impacts may arise. Additional risks that we currently do not know about, or that we currently believe to be immaterial, may also impair our business. Certain statements below are forward-looking statements. See “Special Note Regarding Forward-Looking Statements” in this Quarterly 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 have engaged Cantor to act as strategic advisor for this process. In addition, while we are evaluating several potential opportunities including our own internal obesity program, 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. The value of our hunTR platform may be affected by our termination of the A&R License Agreement with Precigen which returned our rights to the *Sleeping Beauty* technology on which the platform was designed. 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 whether any 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, for our small molecule oral obesity program or should we resume the development of our product candidates of our TCR-T program, 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.

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 nine months ended September 30, 2024, we had a net loss of \$3.9 million, and, as of September 30, 2024, our accumulated deficit since inception in 2003 was \$919.7 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. In connection with our strategic reprioritization, we unilaterally terminated the CRADA in August 2023 and the Patent License in October 2023.

As of September 30, 2024, we had approximately \$1.7 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 third quarter of 2024. 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 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 key employees 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 employees and consultants.

Our ability to consummate a strategic transaction depends upon our ability to retain our remaining employees 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 over 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 remaining employees 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 over 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 employees 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 employees and reduced productivity among remaining employees. 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

We received a Delisting Determination from Nasdaq. Delisting 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 has determined to suspend trading of our common stock on Nasdaq, 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 the Panel. On November 14, 2023, we timely filed a notice requesting a hearing before the Panel to appeal the Delisting Determination. A hearing was initially scheduled for February 15, 2024 and subsequently rescheduled to January 25, 2024. Our common stock continued to trade on the Nasdaq Capital Market Exchange, or the Exchange, under the symbol "TCRT" during this time. Following the hearing, on February 5, 2024, the Panel granted our request to continue listing on the Exchange subject to certain conditions until February 15, 2024. These conditions included the completion of the already shareholder approved 1-for-15 reverse stock split and compliance with the Minimum Bid Price Rule for ten consecutive trading days. We were required to provide prompt notification to the Panel of any "significant" events during the exception period. We executed this reverse stock split on January

31, 2024. On February 16, 2024, we were notified by Nasdaq that we had regained compliance with the Minimum Bid Price Rule. While we are now in compliance, we are now subject to a Mandatory Panel Monitor until February 16, 2025. If we fail to comply with the Minimum Bid Price Rule during this period, we will not be permitted to provide the Staff with a compliance plan and Staff will not be permitted to grant extra time to us to regain compliance. In addition, we would be issued a Delist Determination Letter with the opportunity to request a new hearing with the initial Panel, or a newly convened Hearings Panel if the initial Panel is not available.

If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, deterring broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, the price of our common stock may decline, and although our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. 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 during the monitor period.**

If we receive another delisting notice in respect of the Minimum Bid Price Rule during the monitor period, then we will have to convene a special shareholder meeting to obtain approval for another reverse stock split. There is no guarantee that the Panel will grant us an exception to convene such a meeting. 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 allowed by the Panel should we fail to comply with the Minimum Bid Price Rule during the monitor period, there is no guarantee that the shareholders would approve another reverse stock split. Failure to acquire shareholder approval of a third reverse stock split would negatively effect 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 third reverse stock split, the trading price of our common stock may not meet the Minimum Bid Price Rule**

If we do effect a third reverse stock split, 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 the Panel agrees that implementing a reverse stock split warrants reversing the Staff's delisting determination, regardless of the price at which our common stock would trade following the split.

***In light of the recent reverse stock splits, or if we implement a third reverse stock split during the monitor period, 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 a third reverse stock split to avoid a delisting pursuant to a new Delisting Determination during the monitor period, the liquidity of the shares of our common stock may be affected materially and adversely 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.

****We could lose our listing on the Nasdaq Capital Market if we do not maintain our stockholders' equity. The loss of our Nasdaq listing would in all likelihood make our common stock significantly less liquid and adversely affect its value, including a total loss of value.***

In light of our diminishing cash reserves, we may be delisted from the Nasdaq Capital Market if we cannot maintain our stockholders' equity of at least \$2,500,000. Nasdaq Listing Rule 5550(b)(1) requires that companies listed on the Nasdaq Capital Market maintain stockholders' equity of at least \$2,500,000 (the "Equity Requirement"), or that they meet one of the alternative listing standards: market value of listed securities of at least \$35 million (Rule 5550(b)(2)) or net income of \$500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years (Rule 5550(b)(3)). We do not currently meet either Rule 5550(b)(2) or Rule 5550(b)(3). If we fail to comply with Rule 5550(b)(1), we should have the opportunity to submit a plan to regain compliance and request a hearing before Nasdaq's Hearing Panel for continued listing on Nasdaq which should provide the Company with the opportunity to present its plan to regain compliance with the Equity Requirement, pending the Company's compliance with all criteria for continued listing on the Nasdaq Capital Market. However, there can be no assurance that we would be able to timely regain compliance with the Equity Requirement, and therefore our securities may be delisted from Nasdaq.

In the event of a delisting from the Nasdaq Capital Market, we may seek to have our stock traded in the over-the-counter inter-dealer quotation system, more commonly known as the OTC. OTC transactions involve risks in addition to those associated with transactions in securities traded on the securities exchanges, such as the Nasdaq Capital Market, or, together, Exchange-listed stocks. Many OTC stocks trade less frequently and in smaller volumes than Exchange-listed stocks. Accordingly, our stock would be less liquid than it would be otherwise. Also, the prices of OTC stocks are often more volatile than Exchange-listed stocks. Additionally, institutional investors are usually prohibited from investing in OTC stocks, and it might be more challenging to raise capital.

As further described below, in light of our financial position and our need to raise additional capital, in the event of a delisting from the Nasdaq Capital Market, delisting from the Nasdaq Capital Market would materially limit our ability to obtain additional equity capital. We may need to seek an in-court or out-of-court restructuring of our liabilities. In the event of such restructuring activities, holders of our common stock and other securities will likely suffer a total loss of their investment.

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

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the Nasdaq 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
- as we have terminated the Patent License and the A&R License Agreement or subsequently acquire substantially similar rights, our inability to use the technology previously licensed to us pursuant to the Patent License and the A&R License Agreement.

For our small molecule oral obesity program or should we resume our clinical programs of our TCR-T program, 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 small molecule oral obesity program or should we resume development of our product candidates of our TCR-T program, we may need to recruit, hire and retain qualified personnel.**

Following our strategic reprioritization in August 2023, we have reduced our workforce by over 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 remaining employees 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 small molecule oral obesity program or should we, in the future, resume development of our product candidates of our TCR-T program, 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 license with the National Cancer Institute and our *Sleeping Beauty* license with Precigen. This will affect our ability to quickly resume TCR-T-based clinical trials as we will need to renegotiate this license or obtain approval from FDA to use TCRs that we validate 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.

****The termination of our license with Precigen 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 TCR-T clinical programs, if resumed, depend on patents, know-how, and proprietary technology that are licensed from others, particularly MD Anderson and Precigen, as well as the contributions by MD Anderson under our research and development agreements. The 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 and the A&R License Agreement;
- 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, on acceptable terms, we may be unable to successfully monetize the affected potential products. On October 27, 2023, we provided the NCI the requisite notice of our intent to terminate the Patent License, effective 60 days from such notice, which is now terminated. On October 4, 2024, we terminated the A&R License Agreement with Precigen. If we are unable to reacquire the rights from the NCI or Precigen that we previously had under the Patent License or the A&R License Agreement, 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.

For our small molecule oral obesity program or should we resume development of our product candidates of our TCR-T program, we may not be able to commercialize them, generate significant revenues, or attain profitability.

To date, none of our product candidates have been approved for commercial sale in any country. The process to develop, obtain regulatory approval for, and commercialize potential product candidates is long, complex and costly. For our small molecule oral obesity program or should we resume clinical development of our TCR-T program, unless and until we receive approval from the FDA and/or other foreign regulatory authorities for our product candidates, we cannot sell our products and will not have product revenues. Even if we should in the future resume development of our product candidates of our TCR-T program or for our small molecule oral obesity program and obtain regulatory approval for one or more of our product candidates, if we are unable to successfully commercialize our products, we may not be able to generate sufficient revenues to achieve or maintain profitability or to continue our business without

raising significant additional capital, which may not be available. Our failure to achieve or maintain profitability could negatively impact the trading price of our common stock.

***Our small molecule obesity drug program is very early stage and may not provide an alternative to the terminated TCR-T program in order to enable the Company to continue operations.**

On October 10, 2024, we announced that we are continuing to develop a small molecule oral obesity program. We have engaged a contract development and manufacturing organization (CMDO) to manufacture the active pharmaceutical ingredients, or API, for our small molecular candidates. We anticipate initiating *in vitro* testing of our candidates in the fourth quarter of 2024 and, if successful, we plan to conduct an *in vivo* efficacy study in the first half of 2025, with plans to initiate nonclinical and IND-enabling activities in 2025. Our obesity program development relies on contracting with vendors, who may be untimely or even unsuccessful in completing the tasks for which we have engaged them. Reliance on third party vendors gives us less control over timing, quality and quality control. The manufactured active ingredient may not be manufactured correctly or at a sufficient purity for our *in vitro* or *in vivo* studies. Manufacturing of the material may also be delayed for reasons outside our control. These studies are also dependent on specific data readouts as well as our ability to raise additional capital or obtain a joint venture partner in connection with the development of these assets which we may not be able to secure or finalize in the time(s) needed or at all. Even if sufficient quality and quality of API is manufactured, our *in vitro* or *in vivo* studies may be unsuccessful.

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. Our small molecule oral obesity program or if we resume development of our product candidates of our TCR-T program, 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 our 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 primarily in Houston, Texas. These operations could be subject to power shortages, telecommunications failures, water shortages, hurricanes, floods, earthquakes, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we maintain customary insurance policies that we believe are appropriate. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

For our small molecule oral obesity program, we rely and, should we in the future resume development of our product candidates of our TCR-T program, we 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 collected and stored sensitive data, including legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business-critical information including research and development information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Any such event could compromise our networks, and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Although we have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates, we cannot guarantee that those measures will be successful in preventing any such security incident. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties. 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 of our TCR-T program or for our small molecule oral obesity program, 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 hunTR discovery engine were to experience a cyber-incident resulting in the disclosure or theft of our proprietary screening software or library of TCRs, its 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 CLINICAL TESTING, GOVERNMENT REGULATION AND MANUFACTURING OF OUR PRODUCT CANDIDATES

For our small molecule oral obesity program or should we resume development of our product candidates of our TCR-T program, 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 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.

For our small molecule oral obesity program or should we resume clinical development of our TCR-T program, our clinical trials 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 for our small molecule oral obesity program or if we resume development of our product candidates of our TCR-T program, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic stem cell transplantation, rather than enroll patients in any future clinical trial. Additionally, because our 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, for our small molecule oral obesity program or should we resume development of our TCR-T program.

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 for our small molecule oral obesity program or should we resume clinical development of our TCR-T program, 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 TCRT-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. We cannot be certain if or when we will be able to submit a BLA to the FDA and the delay, or any failure, in completing clinical trials for our product candidates could significantly harm our business.

Our most advanced product candidates were 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, if we resume clinical development of our product candidates, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval of our product candidates or whether such a BLA will be accepted. Because we do not anticipate generating significant revenues unless and until we submit one or more BLAs and thereafter obtain requisite FDA approvals, the timing of our BLA submissions and FDA determinations regarding approval thereof will directly affect if and when we are able to generate significant revenues.

In addition, we have halted development of our 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 of our TCR-T program if resumed, or for our small molecule oral obesity program, may produce undesirable side effects or adverse reactions or events, including potential adverse side effects related to cytokine release. If our product candidates or similar products or product candidates under development by third parties demonstrate unacceptable adverse events, we may be required to halt or delay further clinical development of our product candidates, for our small molecule oral obesity program or should we resume our TCR-T program. 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. For our small molecule oral obesity program should we resume product development our TCR-T program or begin commercialization of either program, 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 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 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 product candidates, including DNA plasmids, which we

used as the vector to insert our TCRs into human T cells. Should we resume TCR-T 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 TCR-T 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 TCR-T 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 TCR-T 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 TCR-T 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 product candidates. We may be unable to consistently manufacture our product candidates to the necessary specifications or in quantities necessary to treat patients in clinical trials, for our small molecule oral obesity program or should we resume the activities for our TCR-T program.

We have limited experience in biopharmaceutical manufacturing. In 2021, we began manufacturing our TCR-T 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 TCR-T product candidates and eliminated positions relating to the same. Accordingly, should we elect to in the future, our ability to resume manufacturing our TCR-T product candidates will depend on our hiring and retaining personnel with the appropriate background and training to manufacture our TCR-T product candidates or our obesity APIs 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 TCR-T 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 TCR-T 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. For our small molecule oral obesity program or if we resume TCR-T 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 TCR-T 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 for our TCR-T program.

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 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 our *Sleeping Beauty* system, a non-viral vector to insert genetic information encoding the TCR construct into the patient's T cells. The TCR construct 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 small molecule oral obesity program or should we resume development of our product candidates of our TCR-T program, any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

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

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of our approved products. The FDA closely regulates the post-approval marketing and promotion of products to ensure that

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

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

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

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

RISKS RELATED TO OUR ABILITY TO COMMERCIALIZE OUR PRODUCT CANDIDATES

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

- Delay commercialization of, and our ability to derive product revenues from, our product candidates;

- Impose costly procedures on us; and
- Diminish any competitive advantages that we may otherwise enjoy.

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

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

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

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

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

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

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

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

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.

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 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 replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. In December 2017, Congress repealed the tax penalty, effective January 1, 2019, for an individual's failure to maintain ACA-mandated health insurance as part of the Tax Act. Further, President Biden issued an executive order that instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the IRA into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and implementing a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact ACA and our business. The ultimate content, timing or effect of any healthcare reform measures on the U.S. healthcare industry is unclear.

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

The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 30, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The IRA delayed the implementation of the rule to January 1, 2032. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2032. In addition, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate price cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source products, beginning on January 1, 2024. Further, in July 2021, the Biden Administration released an executive order that included multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug price reform. The plan sets out a variety of potential legislative policies that Congress could

pursue as well as potential administrative actions by HHS. No legislative or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of the budget reconciliation process. Additionally, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions 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 TCR-T immuno-oncology product candidates may face competition in the future from biosimilars and/or new technologies.

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

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 exclusive rights in the field of cancer treatment to certain U.S. and foreign intellectual property with respect to certain cell therapy and related technologies from MD Anderson. 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. Under the Patent License with the NCI for certain TCRs, the NCI was responsible for the preparation, filing, prosecution, and maintenance of patent applications and patents licensed to us. Although under the Patent License, the NCI was required to consult with us in the preparation, filing, prosecution, and maintenance of all its patent applications and patents licensed to us, we could not guarantee that our comments will be solicited or implemented. On October 27, 2023, we provided the NCI the requisite notice of our intent to terminate the Patent License, effective 60 days from such notice. We no longer have any rights to the technology licensed pursuant to the Patent License. Under our A&R License Agreement, Precigen had the right, but not the obligation, to prepare, file, prosecute, and maintain the patents

and patent applications licensed to us and bore all related costs incurred by it in regard to those actions. Precigen was required to consult with us and keep us reasonably informed of the status of the patents and patent applications licensed to us, and to confer with us prior to submitting any related filings and correspondence. Although under the A&R License Agreement Precigen agreed to consider in good faith and consult with us regarding any comments we may have regarding these patents and patent applications, we could not guarantee that our comments will be solicited or followed. On October 4, 2024, we terminated the A&R License Agreement with Precigen. Without direct control of the in-licensed patents and patent applications, we are dependent on MD Anderson 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. However, we cannot predict or guarantee for either our in-licensed patent portfolios or for Alaunos' patent portfolio:

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

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

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

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

Certain technologies utilized in our research and development programs are already in the public domain. Moreover, a number of our competitors have developed technologies, or filed patent applications or obtained patents on technologies, compositions and methods of use that are relevant to our business and may cover or conflict with our owned or licensed patent applications, technologies or product candidates. Such conflicts could limit the scope of the patents, if any, that we may be able to obtain. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases at all, and because publications of discoveries in the scientific literature lag behind actual discoveries *per se*, neither we nor our licensors can be certain that others have not filed patent applications for technology used by us or covered by our pending patent applications. We cannot know with certainty whether we were the first to make and file for the inventions claimed in our owned patent portfolio, or whether our licensors were the first to make and file for the inventions claimed in our in-licensed patent portfolio. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in the issuance of patents that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. In addition, our own earlier filed patents and applications or those of MD Anderson 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 employees, consultants, advisors and contractors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how, confidential information or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. Moreover, we may not be able to obtain adequate remedies for any breaches of these agreements. Our trade secrets or other confidential information may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or other confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets or other confidential information were to be lawfully obtained or independently developed by competitors, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

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

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

For our small molecule oral obesity program, should we resume development in the future of our TCR-T program, 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 is early-stage technology, and we were in the process of designing and developing

products using this technology. Although we will seek to avoid pursuing the development of products that may infringe any third-party patent claims that we believe to be valid and enforceable, we may fail to do so. Moreover, given the breadth and number of claims in patents and pending patent applications in the field of immuno-oncology and obesity treatments 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 employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

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

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

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

OTHER RISKS RELATED TO OUR COMPANY

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

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

- Our decision to pursue a strategic reprioritization;
- 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 for our small molecule oral obesity program or should we resume clinical development of our TCR-T program;
- 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 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.

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 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 fail to continue publishing research about our business, if they change their recommendations 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.

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

As of September 30, 2024, we had warrants for 26,555 shares of our common stock outstanding at a weighted average exercise price of \$28.50 per share. We are able to grant stock options, restricted stock, restricted stock units, stock appreciation rights, bonus stocks, and performance awards under our 2020 Equity Incentive Plan. As of September 30, 2024, under the 2020 Equity Incentive Plan and the 2012 Equity Incentive Plan, 33,237 shares were issuable upon the exercise of outstanding options at a weighted average exercise price of \$153.79 per share.

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

As of September 30, 2024, our executive officers, directors and holders of five percent or more of our outstanding common stock beneficially owned, in the aggregate, 16.69% 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.

Item 2. Unregistered Sale of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Trading Plans

During the fiscal quarter ended September 30, 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 6. Exhibits

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of Alaunos Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, SEC File No. 001-33038, filed July 17, 2024).
3.2	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).
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+	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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.
++	This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements 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.

By:

/s/ Dale Curtis Hogue, Jr.
Dale Curtis Hogue, Jr.
Interim Chief Executive Officer
(*On Behalf of the Registrant and as Principal Executive Officer and Principal Financial Officer*)
Dated: November 14, 2024

By:

/s/ Ferdinand Groenewald
Ferdinand Groenewald
Vice President, Finance
(*Principal Accounting Officer*)
Dated: November 14, 2024

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER

I, Dale Curtis Hogue, Jr., certify that:

- 1)I have reviewed this Quarterly Report on Form 10-Q 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: November 14, 2024

/s/ Dale Curtis Hogue, Jr.

Dale Curtis Hogue, Jr.
Interim Chief Executive Officer and Director
Principal Executive Officer and
Principal Financial Officer

**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 Quarterly Report of Alaunos Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024, 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*
November 14, 2024
