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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 8, 2023

Alaunos Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-33038**	**84-1475642**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

8030 El Rio Street
Houston, TX 77054
(Address of principal executive offices, including zip code)

(346) 355-4099
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, par value $0.001 per share	TCRT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2023, Alaunos Therapeutics, Inc. (the "Company") issued a press release announcing its financial condition and results of operations for the three months ended September 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02, including Exhibit 99.1, is being "furnished" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 2.02, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

As previously disclosed, on January 4, 2023, the Company received a deficiency letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the bid price for the Company's common stock, par value $0.001 per share (the "Common Stock"), had closed below the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A) (the "Compliance Period Rule"), the Company was provided an initial period of 180 calendar days, or until July 3, 2023 (the "Compliance Date"), to regain compliance with the Bid Price Requirement.

On June 22, 2023, the Company applied to transfer the listing of the Common Stock from the Nasdaq Global Select Market to the Nasdaq Capital Market (the "Transfer"). On July 5, 2023, Nasdaq notified the Company that the Transfer was approved, and that, in connection with the Transfer, the Company was eligible for an additional 180 calendar day period, or until January 2, 2024 (the "Extended Compliance Period"), to regain compliance with the Bid Price Requirement.

On November 8, 2023, the Company received a Staff Delisting Determination letter (the "Delisting Determination") from the Staff notifying the Company that, because the closing bid price for the 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 the 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 Securities and Exchange Commission (the "SEC") to remove the Common Stock from listing and registration under the Securities Exchange Act of 1934, as amended, unless the Company timely requests an appeal of the Delisting Determination to a Nasdaq Hearings Panel (the "Panel").

We intend to timely request a hearing before the Panel to appeal the Delisting Determination and expect a hearing before the Panel to be scheduled where we will seek to remain listed until we are able to consummate a strategic transaction, if ever. Following the hearing, if granted, the Company expects the Panel to issue a written decision that will determine whether the Common Stock will remain listed on Nasdaq.

A timely request for a hearing ordinarily stays the suspension or delisting of the Common Stock, so the Company expects that the Common Stock will continue to trade on the Nasdaq Capital Market under the symbol "TCRT" while the appeal process is pending.

There can be no assurance that the Company's plan will be accepted by the Panel or that, if it is, the Company will be able to regain compliance with the applicable Nasdaq listing requirements. If the Common Stock is delisted, it could be more difficult to buy or sell the Common Stock or to obtain accurate quotations, and the price of the Common Stock could suffer a material decline. Delisting could also impair the Company's ability to raise capital.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the U.S. federal securities laws. Forward-looking statements can be identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "promise" or similar references to future periods. Examples of forward-looking statements in this Form 8-K include, without limitation, statements regarding whether the Company will request a review of the Delisting Determination and the timing of the filing of any Form 25-NSE with the SEC. Forward-looking statements are statements that are not historical facts, nor assurances of future performance. Instead, they are based on the Company's current beliefs, expectations and assumptions regarding the future of its business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent risks and uncertainties, and actual results may differ materially from those set forth in the forward-looking statements. Important factors that could cause actual results to differ include, without limitation, delisting from Nasdaq may adversely impact trading in the Common Stock and the Company's ability to raise financing; the Company has and expects to continue to incur significant losses; the Company's need for additional funding, which may not be available on reasonable terms or at all; and the other important factors described under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, filed with the SEC on November 14, 2023, and its other filings with the SEC. Any forward-looking statement made by the Company in this Form 8-K is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, the Company expressly disclaims any obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Alaunos Therapeutics, Inc., dated November 14, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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 hereunto duly authorized.

Alaunos Therapeutics, Inc.

Date: November 14, 2023

By: /s/ Melinda Lackey
Name: Melinda Lackey
Title: Senior Vice President, Legal and Administration

Exhibit 99.1

Alaunos Therapeutics Announces Third Quarter 2023 Financial Results, Phase 1 Clinical Data and Continued Exploration of Strategic Alternatives

- *TCR-T Library Phase 1/2 trial achieved an 87% disease control rate of eight evaluable patients with metastatic, refractory solid tumors; TCR-T cell therapy was well tolerated in all treated patients*
- *hunTR® discovered new HLA class I and class II restricted TCRs that recognize driver mutations, including KRAS and TP53*
- *Company continues to explore potential strategic alternatives; cost-savings measures expected to extend cash runaway into the second quarter of 2024*

HOUSTON, November 14, 2023 – Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") (Nasdaq: TCRT), today announced financial results for the third quarter ended September 30, 2023. As previously announced, the Company is exploring strategic alternatives with Cantor Fitzgerald & Co. as its strategic advisor. Alaunos continues to reduce spend and cost-savings measures taken to date are expected to extend its cash runway into the second quarter of 2024.

Operational & Corporate Update

Clinical Data from TCR-T Library Phase 1/2 Trial: Eight patients were treated and evaluated in the Company's TCR-T Library Phase 1/2 Trial. Patients with pancreatic (3), colorectal (4) and non-small cell lung cancer (1) were treated, with certain of the pancreatic and colorectal patients also having lung metastases. Overall, the trial showed the Company's T cells were 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 best overall response of stable disease. The total overall response rate was 13% and disease control rate was 87% in evaluable patients with advanced, metastatic, refractory solid tumors (see attached figure). 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, Alaunos announced in August 2023 that it would not pursue any further development of its clinical programs.

hunTR® TCR Discovery Platform Identifies Proprietary TCRs: Alaunos has discovered multiple proprietary TCRs targeting driver mutations through its hunTR® TCR discovery platform. In addition to TCRs that recognize *KRAS* and *TP53* mutations similar to those licensed from the National Cancer Institute, the Company identified additional TCRs that bind to other driver mutations and TCRs that are restricted to additional HLAs. Alaunos believes that the hunTR® library has the potential to allow for the treatment of a large patient population.

Strategic Alternatives: The Company continues 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, the Company has reduced its workforce by approximately 80% to date in order to streamline the organization and to maximize its cash runway.

Third Quarter Ended September 30, 2023, Financial Results

Collaboration Revenue: Collaboration revenue was $0 for the third quarter of 2023, compared to $2.9 million for the third quarter of 2022. The decrease was due to revenue earned under the Solasia License and Collaboration Agreement in 2022 that did not recur in 2023.

Research and Development Expenses: Research and development expenses were $3.7 million for the third quarter of 2023, compared to $7.9 million for the third quarter of 2022, a decrease of approximately 54%. The decrease was primarily due to lower program expenses of $0.8 million as a result of our wind-down of clinical activities, a $0.6 million decrease in employee-related expenses due to our reduced headcount, an accrual adjustment related to our de-prioritized clinical programs of $0.3 million and a $2.5 million milestone payment to MD Anderson in 2022 under the terms of our patent and technology license agreement that did not recur in 2023.

General and Administrative Expenses: General and administrative expenses were $3.6 million for the third quarter of 2023, compared to $3.3 million for the third quarter of 2022, an increase of approximately 9%. The increase was primarily due to higher consulting and professional services expenses of $0.9 million related to increased legal costs, partially offset by a $0.4 million decrease in employee-related expenses due to our reduced headcount and a $0.2 million decrease in insurance fees.

Restructuring Costs: Restructuring costs were $0.4 million for the third quarter of 2023, compared to $0 for the third quarter of 2022 due to severance expenses for terminated employees related to our strategic reprioritization announced in August 2023.

Property and Equipment and Right-of-Use Asset Impairment: Property and equipment and right-of-use asset impairment charges were $1.0 million for the third quarter of 2023, compared to $0 for the third quarter of 2022 due to changes in the intended use of our property and equipment and lease right-of-use asset following the announcement of our strategic reprioritization in August 2023.

Net Loss: Net loss was $8.5 million, or $(0.04) per share, for the third quarter of 2023, compared to a net loss of $8.9 million, or $(0.04) per share, for the third quarter in 2022.

Cash, Cash Equivalents and Restricted Cash: As of September 30, 2023, Alaunos had approximately $11.9 million in cash balances. The Company expects to have sufficient cash resources to fund operations into the second quarter of 2024 as a result of its ongoing strategic reprioritization.

About Alaunos Therapeutics, Inc.

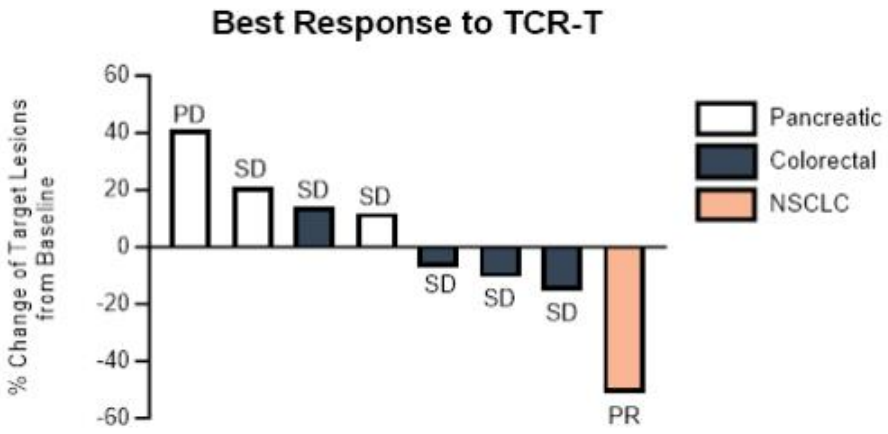
Alaunos Therapeutics is a T-cell receptor (TCR) cell therapy company powered by its hunTR® (human neoantigen T-cell Receptor) discovery platform. hunTR® enables the rapid identification of wholly owned, proprietary TCRs. Using a proprietary high-throughput TCR screening process, hunTR® enables rapid functional validation of TCRs potentially allowing Alaunos to advance new TCRs from the lab to testing in the clinic. For more information, visit www.alaunos.com.

Forward-Looking Statements Disclaimer

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as “may,” “will,” “could,” “expects,” “plans,” “anticipates,” “believes” or other words or terms of similar meaning. These statements include, but are not limited to, statements regarding the Company’s ability to successfully implement its strategic reprioritization or realize any or all of the anticipated benefits once implemented and its ability to successfully consummate any strategic transactions; the completion and impact of the reduction in workforce; the planned renewed focus on the hunTR® TCR discovery platform and its success, including its ability to discover additional TCRs and the ability to monetize any newly discovered TCRs; the wind down of the TCR-T Phase 1/2 Library trial; the Company’s expected cash runway; and the results and potential of the TCR-T Phase 1/2 Library trial and the hunTR® discovery platform. Although the management team of Alaunos believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Alaunos, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, among other things, risks relating to volatility and uncertainty in the capital markets for biotechnology and cell therapy companies; availability of suitable third parties with which to conduct contemplated strategic transactions; whether the Company will be able to pursue a strategic transaction, or whether any transaction, if pursued, will be completed successfully and on attractive terms or at all; whether our cash resources will be sufficient to fund the Company’s foreseeable and unforeseeable operating expenses and capital requirements; changes in the Company’s operating plans that may impact its cash expenditures; the uncertainties inherent in research and development, future clinical data and analysis; the risks associated with reductions in workforce, including reduced morale and attrition of additional employees necessary for the strategic reprioritization; the Company’s exclusive focus on its hunTR® TCR discovery platform; the strength and enforceability of Alaunos’ intellectual property rights; competition from other pharmaceutical and biotechnology companies; and the potential delisting of the Company’s common stock from the Nasdaq Stock Market LLC, as well as risk factors discussed or identified in the public filings with the Securities and Exchange Commission made by Alaunos, including those risks and uncertainties listed in the most recent periodic report filed by Alaunos with the Securities and Exchange Commission. Alaunos is providing this information as of the date of this press release, and Alaunos does not undertake any obligation to update or revise the information contained in this press release whether as a result of new information, future events, or any other reason.

Investor Relations Contact:

ir@alaunos.com


Best Response to TCR-T
% Change of Target Lesions from Baseline
60
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-40
-60
PD
SD
SD
SD
SD
SD
SD
PR
Pancreatic
Colorectal
NSCLC

Alaunos Therapeutics, Inc.
Statement of Operations
(In thousands except per share data)

	For the Three Months Ended September 30 (Unaudited)	
	2023	2022
Collaboration revenue	$ —	$ 2,911
Operating expenses:		
Research and development	$ 3,656	$ 7,893
General and administrative	3,578	3,282
Restructuring costs	419	—
Property and equipment and right-of-use asset impairment	1,011	—
Total operating expenses	8,664	11,175
Loss from operations	(8,664)	(8,264)
Interest expense	—	(841)
Other income, net	188	254
Net loss	(8,476)	(8,851)
Basic and diluted net loss per share	$ (0.04)	$ (0.04)
Weighted average common shares outstanding, basic and diluted	240,046,026	215,098,995

Alaunos Therapeutics, Inc.
Selected Balance Sheet Data
(In thousands)

	September 30, 2023 (Unaudited)	December 31, 2022 (Audited)
Cash and cash equivalents	$ 11,944	$ 39,058
Restricted cash	$ —	$ 13,938
Working capital, excluding restricted cash	$ 8,193	$ 15,695
Total assets	$ 19,440	$ 64,937
Total stockholders’ equity	$ 13,900	$ 38,555