

**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): May 10, 2023**

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

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-33038**  
(Commission  
File Number)

**84-1475642**  
(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 May 10, 2023, Alaunos Therapeutics, Inc. (the “Company”) issued a press release announcing its financial condition and results of operations for the three months ended March 31, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release of Alaunos Therapeutics, Inc., dated May 10, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**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 hereunto duly authorized.

Alaunos Therapeutics, Inc.

Date. May 10, 2023

By: /s/ Melinda Lackey

Name: Melinda Lackey

Title: Senior Vice President, Legal

**Alaunos Therapeutics Reports First Quarter 2023 Financial Results**

- *Actively enrolling patients and manufacturing cryopreserved products for TCR-T Library Phase 1/2 trial; expect to report interim data in the third quarter of 2023*
- *Fully prepaid loan with Silicon Valley Bank; now a debt-free company*
- *Amended exclusive licensing agreement with Precigen, Inc., reflecting the Company's focus on its TCR-T programs and eliminating long-term financial obligations*
- *Company to host conference call today at 9:00 a.m. ET*

**HOUSTON, May 10, 2023** – Alaunos Therapeutics, Inc. (“Alaunos” or the “Company”) (Nasdaq: TCRT), a leading T-cell receptor (TCR) cell therapy company advancing a clinical-stage pipeline of therapeutics for solid tumors, today announced financial results for the first quarter ended March 31, 2023, and provided a corporate update.

“Our TCR-T Library Phase 1/2 trial continues to garner significant interest among patients, physicians and investigators,” said Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. “We’ve been actively enrolling patients and manufacturing cryopreserved products, and we expect to report interim clinical data in the third quarter of this year. As we work to fully realize the long-term potential of our TCR-T platform, we have simplified our corporate structure with the full prepayment of our loan with SVB and the recent agreement with Precigen. We are now moving forward unencumbered by debt or these potential royalties as we seek to transform the treatment of solid tumors.”

**Recent Developments and Upcoming Milestones**

**TCR-T Library Phase 1/2 trial actively enrolling patients:** Alaunos continues to actively enroll patients in its TCR-T Library Phase 1/2 trial targeting KRAS, TP53 and EGFR driver mutations across six solid tumor indications. Early translational data from the first three patients treated in the program will be highlighted in a poster at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 2-6, 2023. Alaunos currently expects to provide an interim data update on multiple new patients in the third quarter of this year as the Company advances the program towards Phase 2 readiness with a recommended Phase 2 dose anticipated by year end 2023.

**Manufactured multiple cryopreserved products:** In the first quarter of 2023, Alaunos enhanced its manufacturing process to move from fresh to cryopreserved cell product enabling greater flexibility for patient scheduling and treatment. To date, the Company has manufactured multiple cryopreserved products with viability, purity and TCR positivity comparable to our prior process.

**Completed full prepayment of amended loan and security agreement with Silicon Valley Bank (SVB):** In May 2023, Alaunos fully prepaid the remaining amounts owed under its term loan with SVB, which was \$11.0 million as of March 31, 2023. With no remaining obligations due to SVB, the restricted cash balance of \$13.9 million as of March 31, 2023, has also been released.

**Amended exclusive license agreement with Precigen, Inc.; Alaunos maintains exclusive rights to TCRs using *Sleeping Beauty* targeting driver mutations:** In April 2023, Alaunos amended its exclusive license agreement with Precigen. Under the terms of the amended agreement, Alaunos maintains exclusive rights to TCRs using *Sleeping Beauty* targeting driver mutations, while Precigen regains the rights to its CAR-T and IL-12 assets. The amended agreement eliminated all commercial sales-based royalties and milestone obligations, in alignment with Alaunos' focus on its priority TCR-T programs.

**Expanded infrastructure of hunTR<sup>®</sup> TCR discovery platform to increase throughput; expect to add three new TCRs in 2023:** In the first quarter of 2023, Alaunos significantly increased the throughput potential of its hunTR<sup>®</sup> TCR discovery platform to further accelerate TCR discovery and validation. New lab equipment and advanced bioinformatics capabilities have multiplied the screening throughput while maintaining a high success rate of TCR discovery. The Company expects to add three new TCRs to its library, potentially bringing the total number of unique TCRs to 15 by the end of 2023.

**Appointed Robert Hofmeister, PhD, MS, to Board of Directors:** In March 2023, Alaunos appointed Robert J. Hofmeister, PhD, MS, to the Company's board of directors. Dr. Hofmeister brings deep expertise in the discovery and development of engineered T-cell receptor therapies as well as a background in cellular immunology and translational science. He is currently Chief Scientific Officer of a stealth early-stage biotechnology company and was most recently Chief Scientific Officer at TCR<sup>2</sup> Therapeutics.

### **First Quarter Ended March 31, 2023, Financial Results**

**Research and Development Expenses:** Research and development expenses were \$6.5 million for the first quarter of 2023, compared to \$5.6 million for the first quarter of 2022, an increase of approximately 17%. The increase was primarily due to incremental manufacturing activities related to the TCR-T Library Phase 1/2 trial and hunTR<sup>®</sup> research efforts of \$1.7 million, partially offset by a \$0.7 million decrease in employee-related expenses.

**General and Administrative Expenses:** General and administrative expenses were \$3.2 million for the first quarter of 2023, compared to \$3.5 million for the first quarter of 2022, a decrease of approximately 10%. The decrease was primarily due to lower professional fees of \$0.2 million.

**Net Loss:** Net loss was \$10.0 million, or \$(0.04) per share, for the first quarter of 2023, compared to a net loss of \$9.8 million, or \$(0.05) per share, for the first quarter of 2022.

**Cash, Cash Equivalents and Restricted Cash:** As of March 31, 2023, Alaunos had approximately \$37.4 million in cash balances, which included restricted cash of approximately \$13.9 million. Based on current operating plans, the Company expects its operating outflows, excluding debt service costs, for 2023 to be between approximately \$35 million and \$40 million. The Company expects to have sufficient cash resources to fund research and development programs and operations into the fourth quarter of 2023.

### **Conference Call and Webcast**

Alaunos will host a conference call and webcast today, May 10, 2023, at 9:00 a.m. ET. Participants may access the live webcast using the link [here](#) or by visiting the "Investors" section of the Alaunos website at [www.alaunos.com](http://www.alaunos.com). To participate via telephone, please register in advance at [this link](#). Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. The event will be archived on the Company's website for approximately 30 days after the call.

## **About Alaunos Therapeutics, Inc.**

Alaunos Therapeutics is a leader in the science of T-cell receptor cell therapy working to revolutionize solid cancer treatment and outcomes. The clinical-stage company's TCR T-cell therapy (TCR-T) is one of the most advanced TCR programs targeting driver mutations in solid tumors with an ongoing Phase 1/2 trial of its TCR-T product candidates across six solid cancers. Alaunos is powered by two proprietary platforms: its elegantly efficient non-viral Sleeping Beauty cell engineering platform; and its hunTR<sup>®</sup> discovery platform, which is expanding its industry-leading library of TCRs against high-frequency driver mutations. Alaunos is a part of an ongoing collaboration with the National Cancer Institute (NCI), part of the National Institutes of Health (NIH), working to advance the science of TCR therapy. For more information, visit [www.alaunos.com](http://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 business and strategic plans, the anticipated outcome of preclinical and clinical studies by the Company or its third-party collaborators, the Company's cash runway and forecasted operating cash flow, the Company's manufacturing capabilities and the timing of the Company's research and development programs, including the expected timeline for enrolling and dosing patients, submitting and receiving approvals on INDs and similar regulatory submissions and the timing and forums for announcing data from the Company's clinical trials. 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, 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, including whether any of Alaunos' product candidates will advance further in the preclinical research or clinical trial process, including receiving clearance from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies to conduct clinical trials and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indication; the strength and enforceability of Alaunos' intellectual property rights; and competition from other pharmaceutical and biotechnology companies; the impacts related to or resulting from recent bank failures and other economic and industry volatility; 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.

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

	Three Months Ended March 31 (Unaudited)	
	2023	2022
Operating expenses:		
Research and development	\$ 6,504	\$ 5,580
General and administrative	3,168	3,505
Total operating expenses	9,672	9,085
Loss from operations	(9,672)	(9,085)
Interest expense	(853)	(683)
Other income (expense), net	477	(20)
Net loss	(10,048)	(9,788)
Basic and diluted net loss per share	\$ (0.04)	\$ (0.05)
Weighted average common shares outstanding, basic and diluted	239,679,352	214,946,569



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

	March 31, 2023 (Unaudited)	December 31, 2022 (Audited)
Cash and cash equivalents	\$ 23,496	\$ 39,058
Restricted cash	\$ 13,938	\$ 13,938
Working capital, excluding restricted cash	\$ 7,183	\$ 15,695
Total assets	\$ 48,638	\$ 64,937
Total stockholders' equity	\$ 29,509	\$ 38,555