

**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 2, 2022**

**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 8.01 Other Events**

On May 2, 2022, Alaunos Therapeutics, Inc. (the “Company”) issued a press release announcing the dosing of the first patient in its TCR-T Library Phase 1/2 Trial targeting *KRAS*, *TP53* and *EGFR* mutations across six solid tumor indications using the Company’s non-viral *Sleeping Beauty* transposon/transposase technology. The Company continues to expect to announce interim data from the TCR-T Library Phase 1/2 Trial in the second half of 2022. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated May 2, 2022.</a>
104	<a href="#">Cover Page Interactive Data File (embedded within the Inline XBRL document).</a>

**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 2, 2022

By: /s/ Melinda Lackey

Name: Melinda Lackey

Title: Senior Vice President, Legal



### **Alaunos Therapeutics Doses First Patient in TCR-T Library Phase 1/2 trial for the Treatment of Patients with Solid Tumors**

- First-in-human non-viral TCR-T cell therapy targeting shared hotspot mutations in solid cancers
- First clinical product manufactured and administered to a patient using the Company's in house cGMP manufacturing facility
- Expect to report initial data in 2H22

**HOUSTON, May 2, 2022** – Alaunos Therapeutics, Inc. (“Alaunos” or the “Company”) (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company today announced that the first patient has been dosed in its TCR-T Library Phase 1/2 trial targeting KRAS, TP53, and EGFR mutations across six solid tumor indications using the Company's *Sleeping Beauty* transposon/transposase technology.

“Dosing the first patient in our TCR-T Library Phase 1/2 trial represents a significant accomplishment for Alaunos. Our team has worked diligently to achieve this milestone and bring our TCR-T cell therapy to cancer patients,” commented Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. “We believe that our adaptive trial design has the potential to allow us to rapidly and cost effectively identify the recommended phase 2 dose and quickly advance studies in the most promising indications. We look forward to an initial data readout in the second half of this year.”

The Phase 1/2 study is being conducted at The University of Texas MD Anderson Cancer Center and is an open label, dose escalation study, with patients being treated in one of three dose cohorts:  $5 \times 10^9$ ,  $4 \times 10^{10}$ ,  $1 \times 10^{11}$  TCR-T cells. The trial is enrolling patients with non-small cell lung, colorectal, endometrial, pancreatic, ovarian, and bile duct cancers that have a matching human leukocyte antigen (HLA) and hotspot mutation pairing in Alaunos' TCR-T library. The main study objectives are to define the maximum tolerated dose, recommended phase 2 dose and safety profile.

Carl June, M.D., Chairman of the Alaunos Scientific Advisory Board added, “This is a significant accomplishment as the first-in-human dosing of a patient with *Sleeping Beauty* TCR-T cells. This approach targeting shared driver mutations that are at the core of cancer provides hope of meaningful clinical responses.”

For more information regarding the trial design please see [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (identifier: NCT05194735).

### **About Alaunos Therapeutics**

Alaunos is a clinical-stage oncology-focused cell therapy company, focused on developing T-cell receptor (TCR) therapies based on its proprietary, non-viral *Sleeping Beauty* gene transfer technology and its TCR library targeting shared tumor-specific hotspot mutations in key oncogenic genes including KRAS, TP53 and EGFR. The Company has clinical and strategic collaborations with The University of Texas MD Anderson Cancer Center and the National Cancer Institute. For more information, please visit [www.alaunos.com](http://www.alaunos.com).

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## **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 Company’s cash runway, and the timing of the Company’s research and development programs, including the anticipated dates for filing INDs, enrolling and dosing patients in and the expected timing for announcing preclinical data and results 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 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 Form 10-K 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:**

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