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): September 21, 2022

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 7.01 Regulation FD Disclosure.

On September 21, 2022, Alaunos Therapeutics, Inc. (the "Company") issued a press release highlighting data from the first patient in its TCR-T Library Phase 1/2 Trial. 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 7.01, 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 7.01, 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.

Exhibit No.	Description
99.1	Press Release, dated September 21, 2022
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. September 21, 2022

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

Alaunos Therapeutics Highlights Data from TCR-T Library Phase 1/2 Trial at the CRI-ENCI-AACR Sixth International Cancer Immunotherapy Conference

- First patient achieved a confirmed partial response with 51.2% tumor regression with TCR-T cell persistence ongoing at 3 months post infusion
- *Sleeping Beauty* TCR-T cell therapy had a manageable safety profile with no dose limiting toxicities observed
- Data to be presented on Friday, September 30 at 9:00am ET in a proffered presentation at the CRI-ENCI-AACR Sixth International Cancer Immunotherapy Conference

HOUSTON, September 21, 2022 – Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company, today announced early clinical data from the first patient in its ongoing TCR-T Library Phase 1/2 trial. The data will be presented during a proffered talk at the CRI-ENCI-AACR Sixth International Cancer Immunotherapy Conference (CICON) being held in New York, NY from September 28 through October 1, 2022.

"The encouraging data from the first patient in our trial highlight the potential of our non-viral TCR-T cell therapies to treat solid tumors even at the lowest doses in the study design," said Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. "Patients with solid tumors represents a large unmet medical need, and the results from the first patient are quite promising that our TCR-T cell therapy may offer them hope. We look forward to treating additional patients and are grateful for the continued support from our investigators, patients and our dedicated team."

Marcelo V. Negrao, MD, Department of Thoracic/Head & Neck Med Onc, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center added, "These clinical data, where a greater than 51% tumor regression in a patient with NSCLC was observed, are encouraging. We believe this data adds to the growing body of evidence indicating that targeting shared tumor-specific hotspot mutations using TCRs has the potential to transform the way we treat solid tumor cancers. In addition, we believe that the manageable safety and tolerability profile is reassuring, and we look forward to continuing enrollment in the study."

The TCR-T Library Phase 1/2 trial is an open label, dose escalation study being conducted at MD Anderson. 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.

Key highlights to be presented:

- First patient dosed was diagnosed with non-small cell lung cancer and had previously progressed on three prior lines of treatment. The patient was germline for HLA-A*11:01 with a KRAS G12D mutation, matching one of the ten TCRs within Alaunos' TCR library.

- The patient received standard cy/flu lymphodepletion[1] prior to an infusion of $9x10^9$ TCR-T cells, which were produced using *Sleepy Beauty* at the Company's in-house cGMP manufacturing facility.
- The patient was confirmed to have achieved a partial response with a regression of 46.3% in target lesions at six weeks, which subsequently deepened to 51.2% at week 12. T-cell persistence was ongoing as of week 12.
- The TCR-T cell therapy was well-tolerated and a manageable safety profile was observed in the first patient.
- The patient experienced grade 2 cytokine release syndrome (CRS) which resolved with nasal cannula oxygen supplementation and did not require anti-IL-6 treatment. Grade 4 thrombocytopenia and grade 3 anemia occurred and were both attributed to the lymphodepletion regimen.

Details of the presentation are as follows:

Title: Objective clinical response by KRAS mutation-specific TCR-T cell therapy in previously treated advanced non-small cell lung cancer
Presenter: Marcelo V. Negrao, MD, Department of Thoracic-Head & Neck Medical Oncology, Division of Cancer Medicine at MD Anderson
Date and Time: Friday, September 30, 2022, 9:00-9:15am ET
Session Title: Session 6: Cellular Therapies: Engineering T cells

The full abstract may be accessed by visiting www.cancerimmunotherapyconference.org.

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 a clinical and strategic collaboration with the National Cancer Institute. For more information, please visit www.alaunos.com.

[1] Cyclophosphamide (60 mg/kg for 2 days) and Fludarabine (25 mg/m^2 for 5 days)

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 manufacturing capabilities and the timing of the Company’s research and development programs, including the expected timeline for enrolling and dosing patients 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 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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