

**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): June 24, 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 1.01 Entry into a Material Definitive Agreement.

On June 24, 2022, Alaunos Therapeutics, Inc. (the “Company”) entered into Amendment #4 (the “Fourth Amendment”) to a Cooperative Research and Development Agreement, dated January 9, 2017, by and among the National Cancer Institute, the Company and Precigen, Inc., as amended (the “CRADA”). The Fourth Amendment, among other things, extends the term of the CRADA until January 9, 2025.

The foregoing summary of the Fourth Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Fourth Amendment, a copy of which, subject to any applicable confidential treatment, will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2022.

Item 7.01 Regulation FD Disclosure.

On June 27, 2022, the Company issued a press release announcing the entry into the Fourth Amendment. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated June 27, 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. June 27, 2022

By: /s/ Melinda Lackey

Name: Melinda Lackey

Title: Senior Vice President, Legal



Alaunos Therapeutics and the National Cancer Institute Extend Cooperative Research and Development Agreement for Development of Personalized TCR-T Cell Therapies To 2025

- *NCI will lead the Company's personalized TCR-T cell therapy program using the Company's proprietary non-viral Sleeping Beauty technology*

HOUSTON, June 27, 2022 – Alaunos Therapeutics, Inc. (“Alaunos” or the “Company”) (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company, today announced that the Company has extended its Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), an institute of the National Institutes of Health, using the Alaunos *Sleeping Beauty* technology through January 2025.

Under the terms of the CRADA, the NCI will work to generate proof of concept utilizing the Company’s proprietary non-viral *Sleeping Beauty* technology for personalized TCR-T cell therapy. In this setting, T-cell receptors (TCRs) that react to the patient’s tumor will be identified from the patient and used to generate a TCR-T cell therapy. This approach could potentially apply to a wide range of solid tumor cancer patients. Alaunos believes that the non-viral *Sleeping Beauty* technology could rapidly and cost effectively produce safe and potent TCR-T cell therapies without the complexity of gene editing or viral approaches. Research conducted under the CRADA will be led by Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI’s Center for Cancer Research.

“We are privileged to extend the productive collaboration with Dr. Rosenberg, a cell therapy pioneer. Dr. Rosenberg and the NCI are working to develop personalized cancer therapies using our novel TCR-T cell platform,” commented Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. “Our collaboration reinforces our commitment to improving the lives of cancer patients with solid tumors. We look forward to continuing our collaborating with Dr. Rosenberg and his team to generate proof of concept in this personalized TCR-T approach.”

Drew Deniger, Ph.D., Vice President, Research & Development at Alaunos added, “Having worked alongside Dr. Rosenberg for many years, I am confident that his team at the NCI will be successful in developing personalized TCR-T therapies using our non-viral *Sleeping Beauty* technology. As the world’s experts in *Sleeping Beauty*, we believe that our non-viral means of adding the TCR to T cells is well suited for a personalized approach, with potential to further increase the addressable population for TCR-T therapies.”

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.

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 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 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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