

**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 16, 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 2.02 Results of Operations and Financial Condition.

On May 16, 2022, Alaunos Therapeutics, Inc. issued a press release announcing its financial condition and results of operations for the three months ended March 31, 2022. 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	Press Release of Alaunos Therapeutics, Inc., dated May 16, 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. May 16, 2022

By: /s/ Melinda Lackey

Name: Melinda Lackey

Title: Senior Vice President, Legal



Alaunos Therapeutics Reports First Quarter 2022 Financial Results

Successfully dosed first patient in TCR-T Library Phase 1/2 trial targeting KRAS, TP53 and EGFR mutations across six solid tumor indications

Will present preclinical data today at the ASGCT 25th Annual Meeting highlighting the potential of mbIL-15 as a potent and more durable TCR-T cell therapy

Will present a trial in progress poster for the TCR-T Library Phase 1/2 trial at the 2022 ASCO Annual Meeting being held from June 2-6, 2022, in Chicago, IL

HOUSTON, May 16, 2022 – Alaunos Therapeutics, Inc. (“Alaunos” or the “Company”) (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company today announced financial results for the first quarter ended March 31, 2022.

“Dosing of the first patient in our TCR-T Library Phase 1/2 trial speaks to the dedication of our entire team and reaffirms our commitment to execution. We are working to continue enrolling patients in the trial and expect to provide an initial look at data later this year,” commented Kevin S. Boyle, Sr., Chief Executive Officer. “We are honored to have two posters supporting our TCR-T platform targeting solid tumors at the upcoming ASGCT and ASCO conferences. We believe we have positioned Alaunos for success and look forward to continued progress.”

Recent Developments and Upcoming Milestones

TCR-T Library Trial: In May 2022, the Company announced that it had dosed the first patient with non-viral TCR-T cells in its TCR-T Library Phase 1/2 trial targeting KRAS, TP53, and EGFR mutations across six solid tumor indications. This is a major milestone for Alaunos as it also represents the first clinical product manufactured and administered to a patient using the Company’s in house cGMP manufacturing facility.

The study is being conducted at The University of Texas MD Anderson Cancer Center and is an open label, dose escalation study, with patients to be treated in one of three dosing cohorts: 5×10^9 , 4×10^{10} , or 1×10^{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. The Company will present a trial in progress poster at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting and expects to report initial data in the second half of 2022. Additional information about the study is available at www.clinicaltrials.gov using the identifier: [NCT05194735](https://clinicaltrials.gov/ct2/show/study/NCT05194735).

Presenting preclinical data supporting membrane bound IL-15 (mbIL-15) at the American Society of Gene & Cell Therapy (ASGCT) 25th Annual Meeting: Today, the Company will present preclinical data for its mbIL-15 program at the ASGCT 25th Annual Meeting. The poster titled, “*Stem-cell memory TCR-T cells targeting hotspot EGFR, KRAS and p53 neoantigens generated through co-expression of membrane-bound Interleukin-15*” highlights the potential of mbIL-15 to establish long-lived tumor-specific TCR-T cells. The Company intends to file an IND application for this program in the second half of 2023.

First Quarter Ended March 31, 2022 Financial Results

Research and Development Expenses: Research and development expenses were \$5.6 million for the first quarter of 2022, compared to \$13.3 million for the first quarter of 2021, a decrease of approximately 58%. The decrease was primarily due to lower program-related costs as a result of the winding down of our IL-12 and CAR-T programs and lower employee related expenses due to our reduced headcount following our strategic restructuring event in the third quarter of 2021.

General and Administrative Expenses: General and administrative expenses were \$3.5 million for the first quarter of 2022, compared to \$8.2 million for the first quarter of 2021, a decrease of approximately 57%. The decrease was primarily due to lower employee related expenses due to our reduced headcount following our strategic restructuring event in the third quarter of 2021 and a decrease in consulting and professional services expenses.

Net Loss: Net loss was \$9.8 million, or \$(0.05) per share, for the first quarter of 2022, compared to a net loss of \$21.6 million, or \$(0.10) per share, for the same period in 2021.

Cash and Cash Equivalents: As of March 31, 2022, Alaunos had approximately \$68.3 million in cash and cash equivalents. The Company anticipates its cash runway will be sufficient to fund operations into the second quarter of 2023. Operating cash burn for the first quarter of 2022 was \$7.8 million compared to \$15.3 million in the first quarter of 2021, a decrease of \$7.5 million or 49%.

Conference Call and Webcast

The conference call can be accessed by dialing 844-309-0618 (United States) or 661-378-9465 (International) with the conference code 2495623. A live webcast may be accessed using the link [here](#), or by visiting the “Investors” section of the Alaunos website at www.alaunos.com. After the live webcast, the event will be archived on the Company’s website for approximately 30 days after the call.

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 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 and forums 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-Q and 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:

Alex Lobo

Stern Investor Relations

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

	For the Three Months Ended March 31 (Unaudited)	
	2022	2021
Operating expenses:		
Research and development	\$ 5,580	\$ 13,336
General and administrative	3,505	8,227
Total operating expenses	9,085	21,563
Loss from operations	(9,085)	(21,563)
Other income (expense), net	(703)	9
Net loss	(9,788)	(21,554)
Net loss applicable to common stockholders	(9,788)	(21,554)
Basic and diluted net loss per share	\$ (0.05)	\$ (0.10)
Weighted average number of common shares outstanding used to compute basic and diluted net loss per share	214,946,569	213,954,665

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

	<u>(unaudited)</u> <u>March 31, 2022</u>	<u>(audited)</u> <u>December 31, 2021</u>
Cash and cash equivalents	\$ 68,255	\$ 76,054
Working capital	\$ 48,538	\$ 62,790
Total assets	\$ 84,991	\$ 94,865
Total stockholders' equity	\$ 49,122	\$ 58,057