

**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): August 15, 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 August 15, 2022, Alaunos Therapeutics, Inc. (the “Company”) issued a press release announcing its financial condition and results of operations for the three months ended June 30, 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 August 15, 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. August 15, 2022

By: /s/ Melinda Lackey

Name: Melinda Lackey

Title: Senior Vice President, Legal



Alaunos Therapeutics Reports Second Quarter 2022 Financial Results

- *Advancing TCR-T Library Phase 1/2 trial targeting KRAS, TP53 and EGFR mutations across six solid tumor indications; plan to present early data in 3Q 2022 at a scientific conference; moving ahead with second dose level*
- *Extended Cooperative Research and Development Agreement for development of personalized TCR-T cell therapies with the National Cancer Institute of the National Institute of Health to 2025*
- *Appointed Abhishek Srivastava, Ph.D. as VP, Technical Operations*
- *Advancing multi-pronged strategy to bolster in-house manufacturing capacity*
- *Operating cash burn in 2Q 2022 was \$8.2 million, a decrease of 62% from the same period last year*

HOUSTON, August 15, 2022 – Alaunos Therapeutics, Inc. (“Alaunos” or the “Company”) (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company today announced financial results for the second quarter ended June 30, 2022.

“The team has made tremendous progress building a strong operational, manufacturing, and clinical foundation over the past year. Our TCR-T Library Phase 1/2 trial is actively enrolling, and I am pleased to announce that we are moving ahead at the second dose level,” commented Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. “The recent hiring of Abhi Srivastava as our VP of Technical Operations strengthens our manufacturing capabilities as we work to increase our manufacturing capacity to support future clinical expansion. In addition to our internal efforts, we were privileged to extend our collaboration with Dr. Rosenberg and the National Cancer Institute to develop personalized cancer therapies using our novel TCR-T cell platform. We believe that Alaunos is poised for long term success. We look forward to presenting early data from our Phase 1/2 trial in the third quarter and remain committed to improving the lives of cancer patients with solid tumors.”

Recent Developments and Upcoming Milestones

TCR-T Library Phase 1/2 Trial: The Company continues to advance its TCR-T Library Phase 1/2 trial targeting *KRAS*, *TP53*, and *EGFR* mutations across six solid tumor indications. In May 2022, the Company announced dosing of the first patient in the trial. The patient has non-small cell lung cancer and was treated with TCR-T cells targeting a *KRAS* G12D mutation. Following a safety review by the safety review committee at the MD Anderson Cancer Center, the Company is now moving ahead at the second dose level. The main study objectives are to define the maximum tolerated dose, recommended Phase 2 dose and safety profile. The Company expects to present early data in the third quarter of 2022. Additional information about the trial is available at www.clinicaltrials.gov using the identifier: [NCT05194735](https://clinicaltrials.gov/ct2/show/study/NCT05194735).

Extended Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) for Development of Personalized TCR-T Cell Therapies: In June 2022, the Company announced that it had extended its CRADA with the NCI, regarding the Company's *Sleeping Beauty* technology, through January 2025. Under the CRADA, the NCI will work to generate proof of concept data utilizing the Company's proprietary non-viral *Sleeping Beauty* technology for personalized TCR-T cell therapies. In this approach, T-cell receptors (TCRs) that react to the patient's tumor are identified from the patient and used in an effort to generate a fully autologous, personalized TCR-T cell therapy. 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.

cGMP Manufacturing Facility: The Company's state-of-the-art good manufacturing practice (cGMP) TCR manufacturing facility is fully operational for the manufacture and release of clinical product. The Company is executing on a multi-pronged strategy to expand its manufacturing capabilities. Alaunos is implementing new standard operating procedures that allow for simultaneous production of multiple products, including further optimizing the manufacturing process by introducing cryopreserved cell products. In addition, the Company is hiring additional staff to support increased manufacturing and is evaluating additional strategies including physically expanding its cGMP footprint.

Corporate Updates: In August 2022, Abhishek Srivastava, Ph.D. was appointed Vice President, Technical Operations. Dr. Srivastava joined Alaunos from Athenex, where he was Vice President, Cell Therapy Development.

Second Quarter Ended June 30, 2022 Financial Results

Research and Development Expenses: Research and development expenses were \$5.9 million for the second quarter of 2022, compared to \$13.6 million for the second quarter of 2021, a decrease of approximately 56%. The decrease was primarily due to lower program-related costs of \$2.0 million as a result of the winding down of the Company's IL-12 and CAR-T programs, a \$5.2 million decrease in employee related expenses due to reduced headcount following the restructuring in the third quarter of 2021, and a \$0.3 million decrease in consulting expenses.

General and Administrative Expenses: General and administrative expenses were \$3.4 million for the second quarter of 2022, compared to \$9.1 million for the second quarter of 2021, a decrease of approximately 62%. The decrease was primarily due to lower employee related expenses of \$5.4 million due to reduced headcount following the restructuring in the third quarter of 2021 and a \$0.2 million decrease in consulting and professional services expenses.

Net Loss: Net loss was \$9.9 million, or \$(0.05) per share, for the second quarter of 2022, compared to a net loss of \$22.7 million, or \$(0.11) per share, for the same period in 2021.

Cash and Cash Equivalents: As of June 30, 2022, Alaunos had approximately \$60.0 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 second quarter of 2022 was \$8.2 million compared to \$21.5 million in the second quarter of 2021, a decrease of \$13.3 million or 62%.

Conference Call and Webcast

Alaunos will host a conference call and webcast today, August 15, 2022, at 8:30am 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. 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. 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 anticipated outcome of preclinical and clinical studies by the Company or its third-party collaborators, the Company’s cash runway, the Company’s manufacturing capabilities, and the timing of the Company’s research and development programs, including the anticipated dates for 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.

Investor Relations Contact:

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

	For the Three Months Ended	
	June 30	
	(Unaudited)	
	2022	2021
Operating Expenses:		
Research and development	\$ 5,937	\$ 13,570
General and administrative	3,429	9,069
Gain on lease modification	(133)	—
Total operating expenses	9,233	22,639
Loss from operations	(9,233)	(22,639)
Interest expense	(740)	—
Other income (expense), net	41	(31)
Net loss	(9,932)	(22,670)
Net loss applicable to common stockholders	(9,932)	(22,670)
Basic and diluted net loss per share	\$ (0.05)	\$ (0.11)
Weighted average number of common shares outstanding, basic and diluted	214,998,893	214,426,406

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

	<u>(unaudited)</u>	<u>(audited)</u>
	June 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 60,011	\$ 76,054
Working capital	\$ 34,586	\$ 62,790
Total assets	\$ 73,931	\$ 94,865
Total stockholders' equity	\$ 40,180	\$ 58,057