Alaunos Therapeutics Announces Second Quarter 2023 Financial Results, Interim Clinical Data and Exploration of Strategic Alternatives

Aug 14, 2023

- *TCR-T Library Phase 1/2 trial achieved an 83% disease control rate of six evaluable patients with metastatic, refractory solid tumors; TCR-T cell therapy was well tolerated in all evaluable patients*
- *Company to wind down TCR-T Library Phase 1/2 trial and concurrently explore potential partnering opportunities for the hunTR® platform as well as broad strategic alternatives*
- *Reducing headcount by approximately 60% while retaining key hunTR® R&D capabilities*

HOUSTON, Aug. 14, 2023 (GLOBE NEWSWIRE) -- Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") (Nasdaq: TCRT), today announced financial results for the second quarter ended June 30, 2023. The Company also announced a strategic reprioritization to focus on its hunTR® TCR discovery platform, wind down its TCR-T Phase 1/2 Library trial and explore broad strategic alternatives for the Company. Alaunos is implementing a cost-savings plan that includes a reduction in workforce by approximately 60%.

"Over the past two years, we have advanced the medical field's understanding of TCR-T cell therapies using our innovative *Sleeping Beauty* technology targeting high-frequency driver mutations," said Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. "We continue to believe that this approach has potential in targeting the heart of cancer growth. However, after a review of the funding needs of our TCR-T Library Phase 1/2 trial and the current financial markets, the Board of Directors has made the difficult decision to limit further drug development under our clinical trial and to focus on our promising hunTR® TCR discovery platform as we explore all strategic alternatives."

Operational & Corporate Update

Interim Clinical Data from TCR-T Library Phase 1/2 Trial: Eight patients have been treated in the Company's TCR-T Library Phase 1/2 trial to date, six of which are evaluable as of today. The trial showed that the Company's T-cells were generally well-tolerated in all evaluable participants and achieved an 83% disease control rate in evaluable patients with metastatic, refractory solid tumors. Disease control is measured by objective responses and stable disease. Persistence of TCR-T cells in peripheral blood was detected in all evaluable patients at last follow-up.

hunTR® TCR Discovery Platform Identifies Proprietary TCRs: Alaunos has discovered multiple proprietary TCRs targeting driver mutations through its hunTR® TCR discovery platform. The hunTR® platform can rapidly interrogate T-cell responses and has the potential to expand to multiple targets or cancer indications. Using hunTR®, the Company has demonstrated the ability to isolate neoantigen specific TCRs from tumor resident T-cells. The presence of these driver mutation specific T-cells in the tumor potentially validates the relevance of the mutated target and safety of the TCR for use in other cancer patients expressing the same neoantigen.

Restructuring Organization and Winding Down TCR-T Library Phase 1/2 Trial: Alaunos has decided to wind down its TCR-T Library Phase 1/2 trial and prioritize the hunTR® platform to explore potential partnering opportunities. Concurrently, the Company is exploring strategic alternatives and has engaged Cantor Fitzgerald & Co. to act as a strategic advisor for this process. Strategic options may include but are not limited to, an acquisition, merger, reverse merger, sale of assets, strategic partnerships, capital raises or other transactions. The Company will reduce its workforce by approximately 60% to streamline the organization, while retaining key R&D capabilities for the hunTR® platform and to assist in the strategic alternatives review process. Alaunos does not intend to comment further on this process unless or until its Board of Directors has approved a definitive course of action or it is determined that other disclosure is appropriate.

Second Quarter Ended June 30, 2023, Financial Results

Research and Development Expenses: Research and development expenses were $5.2 million for the second quarter of 2023, compared to $5.9 million for the second quarter of 2022, a decrease of approximately 13%. The decrease was primarily due to an accrual adjustment related to one of our de-prioritized clinical programs of $0.7 million.

General and Administrative Expenses: General and administrative expenses were $3.0 million for the second quarter of 2023, compared to $3.4 million for the second quarter of 2022, a decrease of approximately 11%. The decrease was primarily due to lower employee-related expenses of $0.1 million due to our reduced headcount, a $0.1 million decrease in consulting and professional services related to lower legal fees and the reduced use of consultants, and a $0.2 million decrease in insurance fees.

Net Loss: Net loss was $8.8 million, or $(0.04) per share, for the second quarter of 2023, compared to a net loss of $9.9 million, or $(0.05) per share, for the second quarter in 2022.

Cash, Cash Equivalents and Restricted Cash: As of June 30, 2023, Alaunos had approximately $18.3 million in cash balances. The Company

expects to have sufficient cash resources to fund operations into the fourth quarter of 2023, after implementing the strategic reprioritization laid out above.

About Alaunos Therapeutics, Inc.

Alaunos Therapeutics is a T-cell receptor (TCR) cell therapy company powered by its hunTR® (human neoantigen T-cell Receptor) discovery platform. hunTR® enables the rapid identification of wholly owned, proprietary TCRs. Using a proprietary high-throughput TCR screening process, hunTR® enables rapid functional validation of TCRs potentially allowing Alaunos to advance new TCRs from the lab to testing in the clinic. For more information, 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 evaluating strategic alternatives and the potential outcomes; the completion and impact of the reduction in workforce; the planned renewed focus on the hunTR® TCR discovery platform and its success, including its ability to discover additional TCRs and the ability to monetize any newly discovered TCRs; the wind down of the TCR-T Phase 1/2 Library trial; and the results and potential of the TCR-T Phase 1/2 Library trial.. 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, risks relating to volatility and uncertainty in the capital markets for biotechnology and cell therapy companies; availability of suitable third parties with which to conduct contemplated strategic transactions; whether the Company will be able to pursue a strategic transaction, or whether any transaction, if pursued, will be completed successfully and on attractive terms or at all; whether our cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital requirements; 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; the risks associated with reductions in workforce, including reduced morale and attrition of additional employees necessary for the strategic reprioritization; the Company's exclusive focus on its hunTR ® TCR discovery platform; the strength and enforceability of Alaunos' intellectual property rights; competition from other pharmaceutical and biotechnology companies; the impacts related to or resulting from recent bank failures and other economic and industry volatility; and the potential delisting of the Company's common stock from the Nasdaq Stock Market LLC, 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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Alaunos Therapeutics, Inc.
Statement of Operations
(In thousands except per share data)

		For the Three Months Ended June 30 (Unaudited)		
		2023		2022
Collaboration revenue	$	4	$	-
Operating expenses:				
Research and development	$	5,186	$	5,937
General and administrative		3,045		3,429
Gain on lease modification		(245)		(133)
Total operating expenses		7,986		9,233
Loss from operations		(7,982)		(9,233)
Interest expense		(1,068)		(740)
Other income, net		277		41
Net loss		(8,773)		(9,932)
Basic and diluted net loss per share	$	(0.04)	$	(0.05)
Weighted average common shares outstanding, basic and diluted		239,797,574		214,998,893

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

		June 30, 2023 (Unaudited)		December 31, 2022 (Audited)
Cash and cash equivalents	$	18,317	$	39,058
Restricted cash	$	-	$	13,938
Working capital, excluding restricted cash	$	13,726	$	15,695
Total assets	$	27,927	$	64,937
Total stockholders' equity	$	21,650	$	38,555