Alaunos Therapeutics Reports Third Quarter 2022 Financial Results

Nov 14, 2022

- *Presented early data highlighting first successful objective clinical response using non-viral Sleeping Beauty TCR-T cell therapy in solid tumors at the CRI-ENCI-AACR Sixth International Cancer Immunotherapy Conference (CICON)*
- *Actively enrolling patients in TCR-T Library Phase 1/2 trial at the second dose level; expect to treat next patient in 4Q22*
- *Expanded manufacturing capacity to produce two products simultaneously*
- *Expect to file Investigational New Drug (IND) amendment in 4Q22 to add two additional TCRs to TCR library and move from a fresh to cryopreserved manufacturing process, reducing manufacturing time by 13%*
- *Company to host conference call today at 8:30 AM ET*

HOUSTON, Nov. 14, 2022 (GLOBE NEWSWIRE) -- Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company today announced financial results for the third quarter ended September 30, 2022.

"Our team has worked diligently over the past year to transform our promising technology and scientific foundation into meaningful clinical progress. We were excited to present early data from our TCR-T Library Phase 1/2 trial at CICON, where we showed for the very first time, an objective clinical response in a solid tumor using a non-viral TCR-T cell therapy. These initial safety, persistence and efficacy data reinforce the promise of our *Sleeping Beauty* TCR-T cell therapy to safely achieve measurable regression in solid tumors, even at the lowest dose," commented Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. "In tandem, we have successfully doubled our manufacturing capacity. We look forward to dosing the next patient in our TCR-T Library Phase 1/2 Trial as well as filing an IND amendment to expand our TCR Library and enhance the speed and flexibility of our manufacturing process using cryopreserved cell products in the fourth quarter."

Recent Developments and Upcoming Milestones

Presented encouraging clinical data from TCR-T Library Phase 1/2 Trial at CRI-ENCI-AACR Sixth International Cancer Immunotherapy Conference (CICON): In September 2022, the Company presented early data from its TCR-T Library Phase 1/2 trial targeting *KRAS*, *TP53*, and *EGFR* mutations across six solid tumor indications. The data represent the first report of a successful TCR-T cell therapy using the non-viral *Sleeping Beauty* system for solid tumors. The Company expects to dose the next patient in the study in 4Q22.

Key highlights include:

- First patient dosed was diagnosed with NSCLC and was treated at dose level 1 with TCR-T cells targeting a *KRAS* G12D mutation. The patient achieved six-month progression-free survival, with a best overall response of objective, partial regression of greater than 50% of target lesions at 12 weeks post-cell therapy.
- Second patient dosed was diagnosed with colorectal cancer and was treated at dose level 2 with TCR-T cells targeting a *TP53* R175H mutation. This patient achieved a best overall response of stable disease at six weeks with 12-week progression-free survival.
- Persistence of TCR-T cells was evident in both patients. Patient 1 had persistence at 24 weeks with approximately 30% of all T-cells being TCR-T cells in the blood. Patient 2 had persistence at 12 weeks with approximately 20% of all T-cells being TCR-T cells in the blood.
- In both patients, the TCR-T cell therapy was well-tolerated and presented a manageable safety profile, with no dose limiting toxicities or immune effector cell-associated neurotoxicity syndrome (ICANS) observed.

Additional information about the trial is available at www.clinicaltrials.gov using the identifier: NCT05194735.

Expanded manufacturing capacity to produce two products simultaneously: The Company continues to execute on its multi-pronged strategy to expand manufacturing capacity. As a result of this initiative, the Company has doubled its existing manufacturing capacity to produce two products simultaneously.

Expect to file IND amendment in 4Q22 to expand its TCR Library and move from a fresh to cryopreserved manufacturing process: Alaunos expects to file an IND amendment in the fourth quarter, which will add two new TCRs to the Company's TCR Library targeting frequent mutations and HLAs. This should allow the Company to increase the potential addressable market for its T-cell therapies. In addition, the Company has successfully completed process qualification runs using cryopreserved cell products to manufacture TCR-T cells, which reduces manufacturing process time from

30 days to 26 days, a 13% decrease. The IND amendment will enable the Company to move to a cryopreserved manufacturing process and add flexibility for patient scheduling and treatment.

Presented data highlighting potential of the Company's hunTR ™ platform to expand its TCR Library at the Society for Immunotherapy of Cancer's (SITC) 37th Annual Meeting: In November 2022, the Company presented a poster at the SITC annual meeting, highlighting its proprietary hunTR ™ (human neoantigen T-cell Receptor) platform. hunTR ™ is a high-throughput screening process that uses state-of-the-art bioinformatics and next generation sequencing to interrogate and deconvolute thousands of single T cells simultaneously. In the study, Alaunos evaluated hundreds of thousands of TCR+HLA+neoantigen permutations in nine patients across colorectal, endometrial and breast cancers. All patients screened had at least one detectable neoantigen-reactive TCR, including one shared *KRAS* mutation. Further screening of additional patients only for *KRAS* mutations resulted in discovery of KRAS-G12V reactive TCRs. The Company plans to expand the application of hunTR to screen for additional shared *KRAS*, *TP53*, and *EGFR* mutations in order to rapidly advance new TCR library candidates from the lab through to clinical translation.

Third Quarter Ended September 30, 2022 Financial Results

Collaboration Revenue: Collaboration revenue was $2.9 million for the third quarter of 2022, compared to $0.4 million for the third quarter of 2021, an increase of 631%. The increase was primarily due to the achievement of sales-based milestones of darinaparsin in Japan, which was largely offset by a one-time corresponding $2.5 million Research & Development expense.

Research and Development Expenses: Research and development expenses were $7.9 million for the third quarter of 2022, compared to $14.5 million for the third quarter of 2021, a decrease of approximately 46%. Research and Development expenses during the third quarter of 2022 included a one-time $2.5 million expense as a result of the achievement of sales-based milestones of darinaparsin in Japan.

General and Administrative Expenses: General and administrative expenses were $3.3 million for the third quarter of 2022, compared to $8.2 million for the third quarter of 2021, a decrease of approximately 60%.

Net Loss: Net loss was $8.9 million, or $(0.04) per share, for the third 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 September 30, 2022, Alaunos had approximately $37.8 million in cash and cash equivalents and restricted cash of $13.9 million. Operating cash burn for the third quarter of 2022 was $6.1 million compared to $9.6 million in the third quarter of 2021, a decrease of $3.4 million or 36%.

Conference Call and Webcast

Alaunos will host a conference call and webcast today, November 14, 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 a clinical and strategic collaboration with 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 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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Statement of Operations
(In thousands except per share data)

		For the Three Months Ended September 30 (Unaudited)		
		2022		2021
Collaboration revenue	$	2,911		398
Operating expenses:				
Research and development	$	7,893	$	14,521
General and administrative		3,282		8,173
Total operating expenses		11,175		22,694
Loss from operations		(8,264)		(22,296)
Interest expense		(841)		(444)
Other income, net		254		7
Net loss		(8,851)		(22,733)
Basic and diluted net loss per share	$	(0.04)	$	(0.11)
Weighted average common shares outstanding, basic and diluted		215,098,995		214,542,465

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

		(unaudited)		(audited)
		September 30, 2022		December 31, 2021
Cash and cash equivalents	$	37,807	$	76,054
Restricted cash	$	13,938	$	-
Working capital, excluding restricted cash	$	8,698	$	62,790
Total assets	$	67,344	$	94,865
Total stockholders' equity	$	32,113	$	58,057