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): January 9, 2023

Alaunos Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-33038**	**84-1475642**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 7.01. Regulation FD Disclosure

On January 9, 2023, Alaunos Therapeutics, Inc. (the "Company") began using an updated corporate presentation at the 41st Annual J.P. Morgan Healthcare Conference. A copy of the presentation 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 8.01. Other Events

On January 9, 2023, the Company issued a press release highlighting its strategic priorities and anticipated milestones for 2023. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Presentation, dated January 2023.
99.2	Press Release of Alaunos Therapeutics, Inc. dated January 9, 2023.
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. January 9, 2023

By: /s/ Melinda Lackey
Name: Melinda Lackey
Title: Senior Vice President, Legal

Exhibit 99.1

ALAUNOS™ THERAPEUTICS

Attacking Solid Tumors with Novel TCR-T Cell Therapies

January 2023

Forward Looking Statements

This presentation 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 Alaunos Therapeutics, Inc.'s ("Alaunos" or "the Company") business and strategic plans, the Company's ability to raise capital, and the timing of the Company's research and development programs, including the anticipated dates for enrolling and dosing patients in 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. We are providing this information as of the date of this presentation, and Alaunos does not undertake any obligation to update or revise the information contained in this presentation whether as a result of new information, future events, or any other reason.

Delivering the Promise:
Leading the Fight Against Solid Tumors with TCR-T

2022

Significant Accomplishments

First TCR-T objective clinical response in solid tumors

Doubled addressable market

Doubled manufacturing capacity

Validated hunTR®

2023

Anticipated Milestones

Phase 2 readiness

Expand TCR library to 15

File IND for mbIL-15 TCR-T

2024+

Building for the Future

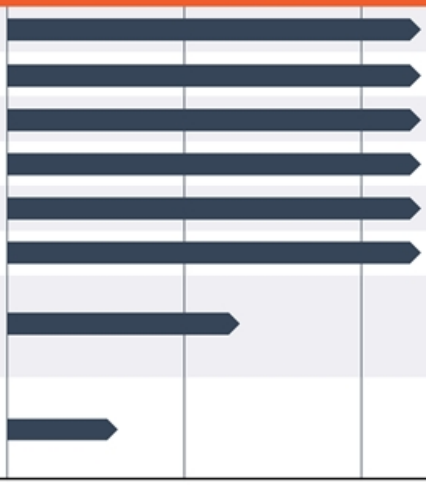
Pivotal clinical trials

Combination therapies

Treat patients with multiple TCRs

Comprehensive TCR-T Platform with Multiple Solid Tumor Programs in Pipeline

PROGRAM	TARGETS	INDICATION	PRECLINICAL	IND-ENABLING	PHASE 1	PHASE 2
Library TCR-T Cell Therapy	***KRAS*** *G12D & G12V* ***TP53*** *R175H, R248W, R273C & Y220C* ***EGFR*** *E746-A750del*	Lung				
		Colon/Rectum				
		Endometrium				
		Pancreas				
		Ovary				
		Bile Duct				
mbIL-15 TCR-T Cell Therapy	***KRAS & TP53*** Mutations	Solid Tumors				
Multiplex TCR-T Cell Therapy	Multiple targets per patient	Solid Tumors				

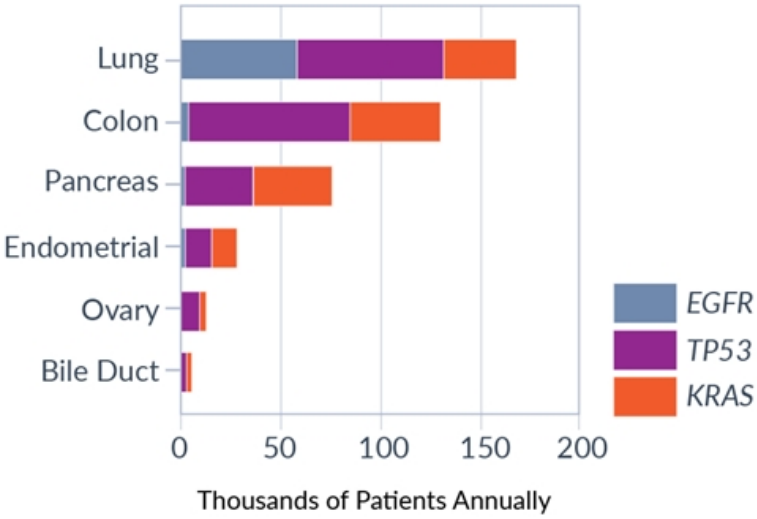


ALAUNOS THERAPEUTICS

Hotspot Mutations are Ideal Targets for TCR-T Cells to Treat Solid Tumors

Target	Examples	Key Advantages	Key Disadvantages
Hotspot Mutations	**Mutated *EGFR*, *KRAS* or *TP53***	• **Drives cancer** • **Highly expressed targets** • **Not on normal tissue** • **Large addressable market**	• **Single targets**
Tumor Associated Antigens	NY-ESO-1, MAGE, PRAME, MART-1, gp100	• Overexpressed on multiple cancer types	• Small addressable market • Potential cross reactivity with normal tissues
Viral Antigens	HPV, EBV, HBV	• Not on normal tissues • Highly expressed target	• Limited to few cancers • Immune editing from chronic viral infection
Individualized Mutations	Mutations expressed by patient's cancer	• Treatment of multiple targets • Large addressable market	• Long time to treatment • Labor intensive • Inherent difference between patients

KRAS, *TP53*, *EGFR* Mutations are Commonly Expressed in Targeted Solid Tumor Indications



Nearly 2 million solid tumors cases diagnosed in United States annually

High frequency tumor targets, not expressed in normal tissues

These six indications represent ~600,000 new cases per year

Source: Most recent catalogue of Somatic Mutations in Cancer (COSMIC) database

ALAUNOS THERAPEUTICS

Confirmed Responses from Leading Academic Institutions Corroborate Targeting Hotspot Mutations with TCR-T Cells

The NEW ENGLAND JOURNAL of MEDICINE

BRIEF REPORT

Neoantigen T-Cell Receptor Gene Therapy in Pancreatic Cancer

Rom Leidner, M.D., Nelson Sanjuan Silva, B.S., Huayu Huang, M.S., David Sprott, B.S., Chunhong Zheng, Ph.D., Yi-Ping Shih, Ph.D., Amy Leung, B.S., Roxanne Payne, M.N., Kim Sutcliffe, B.S.N., Julie Cramer, M.A., Steven A. Rosenberg, M.D., Ph.D., Bernard A. Fox, Ph.D., Walter J. Urba, M.D., Ph.D., and Eric Tran, Ph.D.

Greater than 70% tumor reduction of metastatic pancreatic cancer six months after infusion of KRAS-G12D and HLA-C*08:02 reactive TCR-T cells

CANCER IMMUNOLOGY RESEARCH | RESEARCH ARTICLE

Adoptive Cellular Therapy with Autologous Tumor-Infiltrating Lymphocytes and T-cell Receptor–Engineered T Cells Targeting Common p53 Neoantigens in Human Solid Tumors

Sanghyun P. Kim[1], Nolan R. Vale[1], Nikolaos Zacharakis[1], Sri Krishna[1], Zhiya Yu[1], Billel Gasmi[2], Jared J. Gartner[1], Sivasish Sindiri[1], Parisa Malekzadeh[1], Drew C. Deniger[1], Frank J. Lowery[1], Maria R. Parkhurst[1], Lien T. Ngo[1], Satyajit Ray[1], Yong F. Li[1], Victoria Hill[1], Maria Florentin[1], Robert V. Masi[1], Biman C. Paria[1], Noam Levin[1], Alakesh Bera[1], Elizabeth A. Hedges[1], Agnes Choi[1], Praveen D. Chatani[1], Anup Y. Parikh[1], Shoshana Levi[1], Samantha Seitter[1], Yong-Chen Lu[1], Zhili Zheng[1], Todd D. Prickett[1], Li Jia[3], Jonathan M. Hernandez[4], Chuong D. Hoang[5], Paul F. Robbins[1], Stephanie L. Goff[1], Richard M. Sherry[1], James C. Yang[1], and Steven A. Rosenberg[1]

55% tumor reduction of metastatic breast cancer six months after infusion of TP53-R175H and HLA-A*02:01 reactive TCR-T cells

Alaunos is the only company in the clinic with these TCRs

Sources: Leidner R et al. N Engl J Med. 2022 Jun 2;386(22):2112-2119. doi: 10.1056/NEJMoa2119662.
Kim SP et al. Cancer Immunol Res. 2022 Jun 24:OF1-OF15. doi: 10.1158/2326-6066.CIR-22-0040.

ALAUNOS THERAPEUTICS

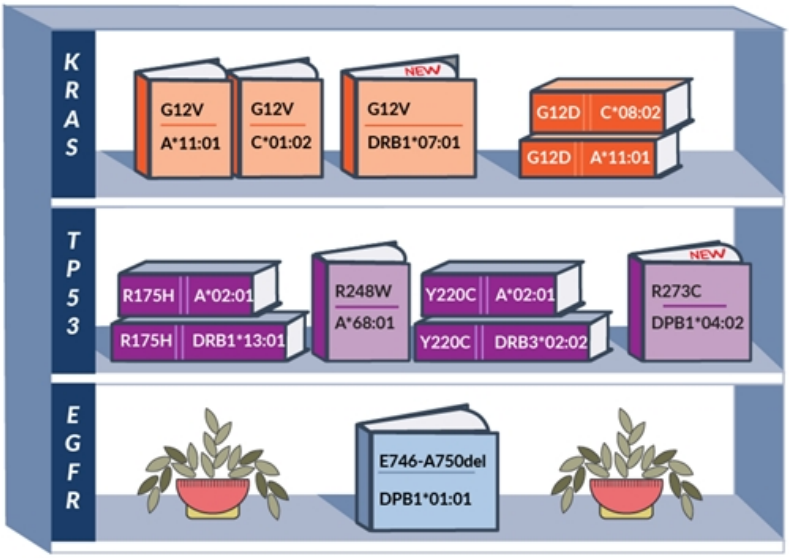
Differentiated Approach to Convert Natural T-Cell Responses into TCR-T Cell Therapy for a Broad Patient Population

Patient 1 with Target A

TCR Source	TCR Library	Manufacture	TCR-T Cell Therapy
Natural TIL Response to Target A	1. Isolate Reactive TCR to Target A 2. Make *Sleeping Beauty* TCR Transposon 3. Add to Library of Pre-Made TCRs	Autologous TCR-T Cells Reactive to Target A	Multiple Patients with Target A

ALAUNOS THERAPEUTICS

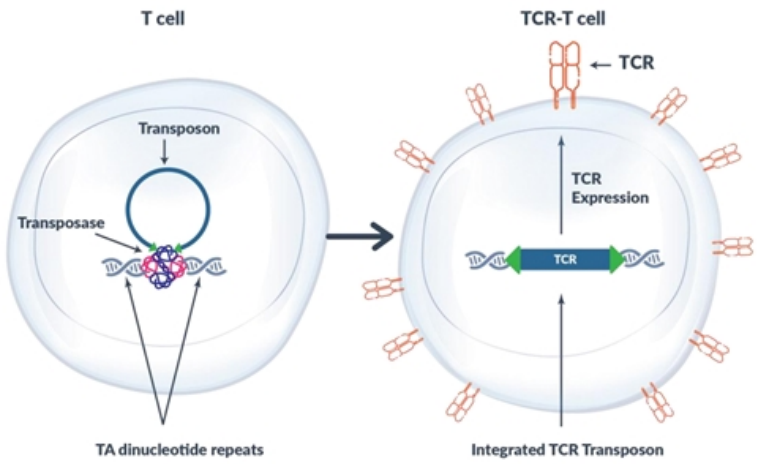
Unparalleled TCR Library Captures Both High Frequency Mutations and HLA Types



- Recently added TCRs via IND amendment:
  KRAS-G12V and DRB1*07:01
  TP53-R273C and DPB1*04:02
- Our TCR library contains mutations from genes that are known to drive cancer and are highly expressed by tumors
- Mutations in our library are among the most frequent and most mutated genes in solid tumors
- HLAs that present our mutations are prevalent in the United States

ALAUNOS THERAPEUTICS

Non-viral *Sleeping Beauty* Platform Well Suited for Manufacturing TCR-T Cells without Complexity of Gene Editing



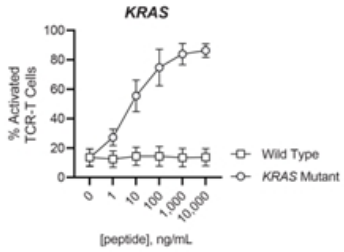
- Efficient, essentially random integration without complexity of gene editing or viral approaches
- Rapid, cost-effective manufacturing
- Flexible approach to add TCRs; attractive choice for library
- Platform can accommodate large transgene size
- Expected to be scalable for commercialization

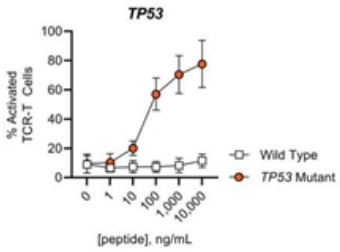
TCR-T Cells Recognize *KRAS*, *TP53*, *EGFR* Mutations and Kill Solid Tumor Cells

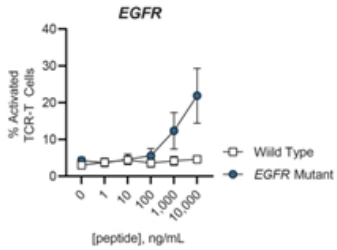
Powerful TCRs:
Naturally-occurring, high avidity TCRs recognize low levels of neoantigens

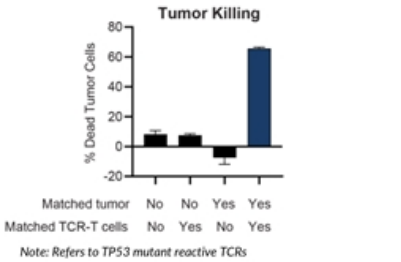
No off-target toxicity observed:
Specificity for the mutation with negligible recognition of wild type sequences

Tumor killing:
Recognition of tumor cells that express mutation and HLA





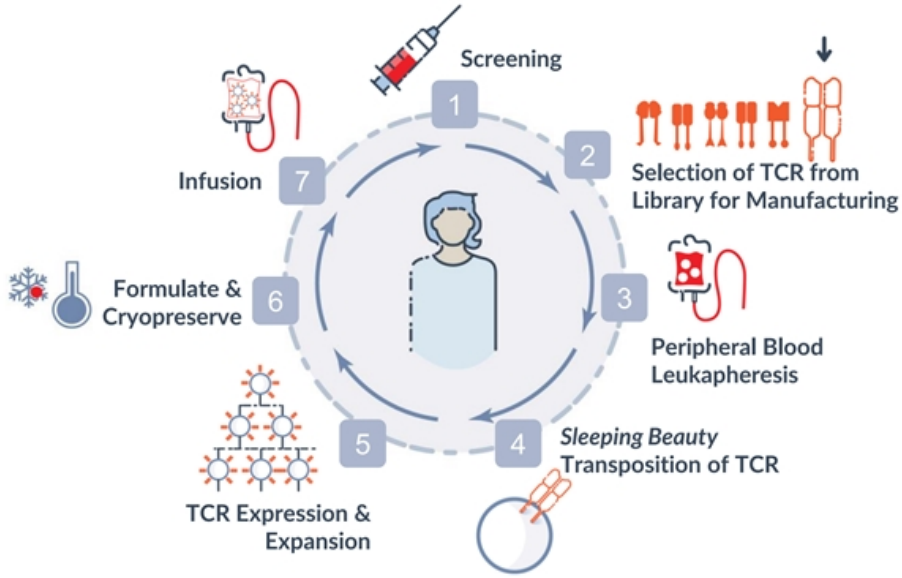




Note: Refers to TP53 mutant reactive TCRs

ALAUNOS THERAPEUTICS

TCR-T Cell Products are Manufactured with a TCR Matched to Each Patient's Tumor Mutation and HLA Type



ALAUNOS THERAPEUTICS

Universal, In-House Manufacturing Platform Delivers High Quality TCR-T Cell Products

	Patient 1	Patient 2	Patient 3
Mutation	KRAS-G12D	TP53-R175H	KRAS-G12V
Indication	Lung	Colorectal	Pancreatic
Dose Level	One	Two	Two
Viability	97%	93%	93%
Total TCR-T Cells	9 Billion	64 Billion	58 Billion
CD3+ Purity	99.7%	99.7%	99.1%
TCR+	95%	92%	91%

Ongoing Process Optimization

- Automation and closed process steps to increase throughput
- Reduction in overall manufacturing days and cost
- Commercially viable process

First-in-Human TCR-T Clinical Trial Actively Enrolling with Innovative Library Approach

Phase 1

- Defines safety and dose with any TCR and any indication
- Enrolling in one of three dose cohorts: 5, 40 and 100 billion TCR-T cells

Phase 2

- Defines efficacy at recommended dose with any TCR in library
- Each cancer type will be a distinct cohort

Pivotal

- Selected indications and selected TCRs with efficacy in Phase 2
- IND can start while Phase 2 continues for other indications/TCRs

Vision for Commercial Product

- Multiple TCRs for use in multiple cancer types
- Early guidance from FDA supports our approach

First-in-Human Confirmed Response in Solid Tumors by *Sleeping Beauty* TCR-T Cell Therapy

SAFETY

Manageable safety profiles in first two dose levels

No DLTs

No ICANs

PERSISTENCE

Persisting TCR-T cells (20%-30%) in blood

TCR-T cells trafficking to tumor

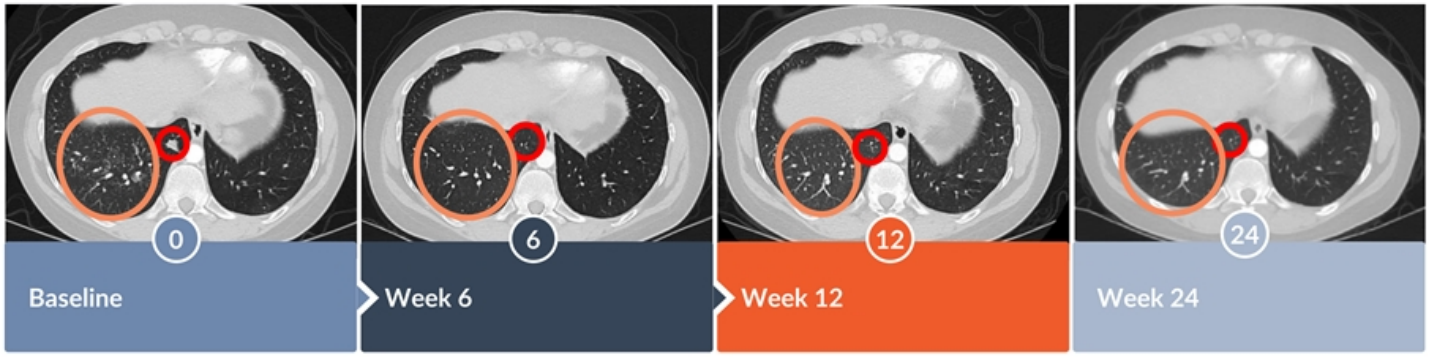
Maintenance of mutation and HLA post-treatment

EFFICACY

First TCR-T cell response in checkpoint inhibitor refractory NSCLC (>50% reduction)

Six-month progression-free survival comparable to approved KRAS drug

Patient 1 Showed Durable, Complete Resolution of NSCLC Lesion Through Six Months



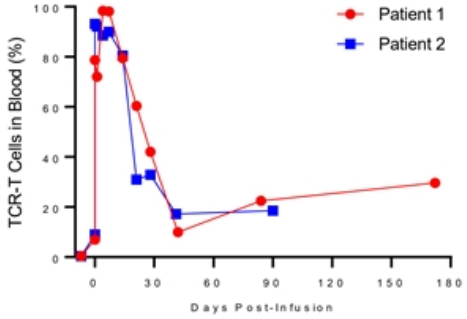
- Patient 1 had multiple lines of prior therapy and was refractory to checkpoint inhibitors
- Treated with 9 billion TCR-T cells (dose level 1) targeting KRAS-G12D and HLA-A*11:01 with manageable safety profile
- Confirmed partial response; patient is now off-study after six-month progression-free survival

Red circles represent target lesions, orange circles represent non-measurable disease

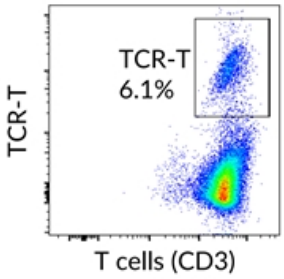
ALAUNOS THERAPEUTICS

TCR-T Cells Persist in Blood and Traffic to Tumor Microenvironment

TCR-T Cell Persistence in Blood



Patient 1:
Six-month Tumor Biopsy



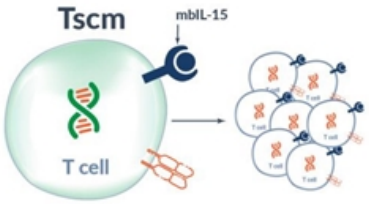
- Mutation and HLA were present in post-treatment tumors
- TCR-T cells were detected in peripheral blood at last follow-up
- Tumor trafficking six months after infusion observed

TCR-T cells from biopsy were grown in lab before analysis

ALAUNOS THERAPEUTICS

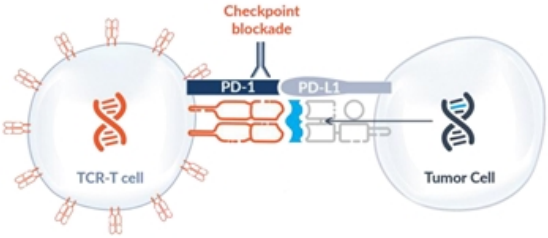
Next Generation TCR-T Efforts Aim to Deepen Clinical Responses

Augmenting TCR-T Survival via Co-Expression of mbIL-15



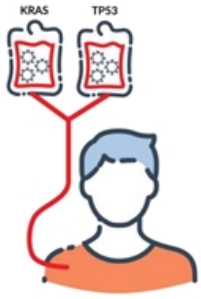
Regeneration of effector TCR-T cells in the tumor

Combine TCR-T and Immune Checkpoint Inhibitors



Reinvigorate TCR-T cells in the tumor microenvironment

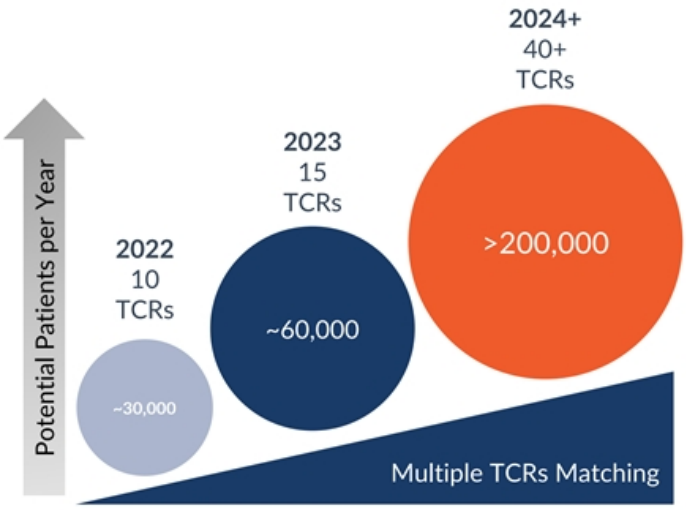
Multiple TCRs infused into the Same Patient



Attack multiple targets on the tumor to potentially synergize TCR-T

ALAUNOS THERAPEUTICS

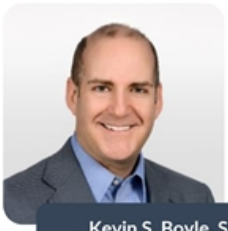
hunTR® Potentially Expands TCR Library, Increases Addressable Market and Enables Multiplexed TCR-T Cell Therapy



- Add new HLAs to existing mutations and add more key mutations within *EGFR*, *KRAS*, *TP53*
- Matching data from clinical efforts inform which HLA/mutation combinations to prioritize
- *Sleeping Beauty* expected to allow for cost-effective and efficient expansion of TCR library for clinic
- Expect out-licensing opportunities of selected proprietary TCRs

ALAUNOS THERAPEUTICS

Experienced Management Team



Kevin S. Boyle, Sr.
Chief Executive Officer

Melinda Lackey
SVP Legal

Drew Deniger, PhD
VP Research & Development

Abhishek Srivastava, PhD
VP Technical Operations

Mike Wong
VP Finance

2023 Milestones Designed to Retain Our Leadership Position in TCR-T Cell Therapy for the Treatment of Solid Tumors

Advance TCR-T Library trial to Phase 2

Optimize manufacturing process towards commercial scalability

New IND for mbIL-15 TCR-T

Expand TCR Library to 15 TCRs

Translational assessment-driven next gen TCR-T

ALAUNOS THERAPEUTICS

Alaunos Therapeutics Highlights Strategic Priorities and Anticipated Portfolio Milestones for 2023

- *Announcing addition of two new TCRs to the library, estimated to double the addressable market; plans to further expand TCR library using hunTR® TCR discovery platform*
- *Increasing patient enrollment to advance TCR-T Library Program towards Phase 2 using high value TCRs targeting common hotspot mutations in six solid tumor indications*
- *Executing against multi-pronged strategy to expand and optimize manufacturing capabilities and processes towards commercial scalability*
- *Advancing our mbIL-15 program towards an anticipated IND filing in the second half of 2023*

HOUSTON, January 9, 2022 – Alaunos Therapeutics, Inc. ("Alaunos" or the "Company") (Nasdaq: TCRT), a clinical-stage oncology-focused cell therapy company today highlights its expected milestones and strategic priorities for 2023.

"Achieving the first-in-human objective clinical response in a patient with a solid tumor using a non-viral TCR-T cell therapy made for an exciting 2022. We believe we are well positioned to increase the pace of enrollment in 2023 and with the addition of two new TCRs to our library we have doubled the potential addressable market of our therapy," commented Kevin S. Boyle, Sr., Chief Executive Officer of Alaunos. "In December we treated our third patient, a pancreatic patient, with a KRAS-G12V mutation. The year ahead will focus on increasing patient enrollment with an aim towards advancing the program to Phase 2 readiness. We are excited about our progress to date and as leaders in the TCR-T cell therapy space we look forward to bringing the promise of our therapies to even more patients in need."

Anticipated 2023 Milestones and Strategic Priorities

Expand TCR library using hunTR® TCR discovery platform to increases addressable market: In the fourth quarter of 2022, the Company submitted an IND amendment to the U.S. Food and Drug Administration (FDA) adding two new TCRs to its clinical trial targeting frequent mutations and HLAs, with the potential to double the addressable market of its TCR-T program. The addition of these new TCRs highlights our strategy to add both more HLAs to existing mutations (KRAS-G12V and HLA-DRB1*07:01) and new mutations within our targeted gene families (TP53-R273C and HLA-DPB1*04:02). In 2023, the Company expects to further expand its library with exclusively owned TCRs targeting recurrent hotspot mutations in *KRAS*, *TP53* and *EGFR*.

Advance TCR-T library program to Phase 2 readiness: The Company continues to actively enroll patients in its TCR-T Library Phase 1/2 trial targeting *KRAS*, *TP53*, and *EGFR* hotspot mutations across six solid tumor indications. In September 2022, the Company announced the first objective clinical response from a TCR-T cell therapy using non-viral *Sleeping Beauty* targeting solid tumors. The Company successfully dosed its third patient in the trial in December 2022 and expects to enroll multiple patients in the first half of 2023. Alaunos anticipates providing an interim data update by mid-2023 as it works towards advancing the program into Phase 2.

Optimize manufacturing process towards commercial scalability: The Company continues to execute on its multi-pronged strategy to expand manufacturing capacity and efficiency. The Company doubled its manufacturing capacity in 2022 allowing for production of two products simultaneously. The Company also filed an IND amendment to move from fresh to cryopreserved product and expects to begin implementing this change in the first half of 2023. The use of cryopreserved cell products will reduce manufacturing process time from 30 days to 26 days, a 13% decrease, while increasing flexibility for patient scheduling and treatment. The Company has ongoing initiatives to optimize the process and further reduce the manufacturing time.

Explore next generation TCR-T cell therapy approaches to deepen clinical responses: The Company is advancing its mbIL-15 TCR-T cell therapy program towards an IND filing anticipated in the second half of 2023. The Company believes mbIL-15 has the potential to increase the survival of TCR-T cells in the harsh tumor microenvironment and deepen clinical responses. In addition, Alaunos continues to conduct translational assessments of treated patients to guide next generation TCR-T therapy approaches including potential combination and multiplexed TCR-T cell therapies.

Cash Position and Financial Guidance

Alaunos ended the fourth quarter of 2022 with unaudited cash and cash equivalents of approximately $39.1 million and restricted cash of approximately $13.9 million. Based on current operating plans, the Company expects its operating cash flow for 2023 to be between approximately $35 million and $40 million. The Company expects to have sufficient cash resources to fund research and development programs and operations into Q4 2023.

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.

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 forecast operating cash flow, 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, submitting and receiving approvals on INDs and similar regulatory submissions 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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