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): March 17, 2022 (March 15, 2022)

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 1.01 Entry into a Material Definitive Agreement.

On March 15, 2022, Alaunos Therapeutics, Inc. (the "Company") entered into Amendment #3 (the "Third Amendment") to a Cooperative Research and Development Agreement, dated January 9, 2017, by and among the National Cancer Institute, the Company and Precigen, Inc., as amended (the "CRADA"). Pursuant to the Third Amendment, the term of the CRADA is extended retroactively for one year, from January 9, 2022 to January 9, 2023. In addition, the Third Amendment makes certain administrative changes, including the Company's name, principal investigator and address.

The foregoing summary of the Third Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Third Amendment, a copy of which, subject to any applicable confidential treatment, will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Item 7.01 Regulation FD Disclosure.

On March 17, 2022, the Company's Chief Executive Officer, Kevin S. Boyle Sr., and Vice President of Research & Development, Drew Deniger, gave a presentation at the Oppenheimer 32nd Annual Healthcare Conference. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation, dated March 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. March 17, 2022

By: /s/ Kevin S. Boyle, Sr.
Name: Kevin S. Boyle, Sr.
Title: Chief Executive Officer

Exhibit 99.1

ALAUNOS™ THERAPEUTICS

Attacking Solid Tumors with Novel TCR-T Cell Therapies

Oppenheimer 32nd Annual Healthcare Conference

March 2022

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.

Shareholder Value Creation:
A Clinical Stage TCR-T Company Targeting Solid Tumors

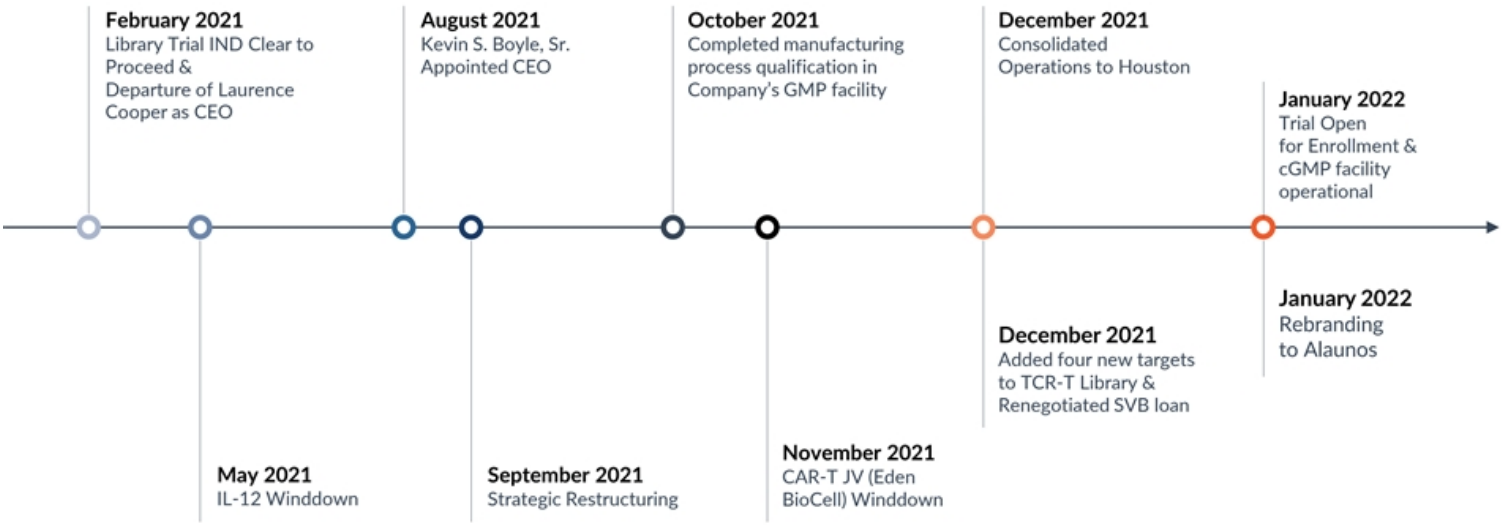
Weaponizing the immune system with powerful TCRs to treat solid tumors

Targeting driver mutations using T cells genetically modified with proprietary non-viral *Sleeping Beauty* platform

Vision 2022 – Execution Mindset, Delivering Results

1. Phase 1/2 TCR-T Library Trial Enrolling; FPI anticipated 1H22, interim data expected 2H22
2. Clinical Library of 10 TCRs (*KRAS*, *TP53*, *EGFR*) Targeting Six Solid Tumor Indications
3. Utilize internal cGMP Manufacturing Facility For TCR-T Library Trial
4. Proprietary TCR Discovery Platform, hunTR™, Expanding and Advancing the Pipeline

From Ziopharm to Alaunos:
Focused and Executing on Advancing our Novel TCR-T Platform



ALAUNOS THERAPEUTICS

TCR-T Platform with Multiple Solid Tumor Programs in Pipeline

PROGRAM	TARGETS	INDICATION	DISCOVERY	PRECLINICAL	IND-ENABLING	PHASE 1
Library TCR-T cell Therapy (Company Sponsored at MDACC)	*KRAS*, *TP53* & *EGFR* Hotspot Mutations	Lung				
		Colon/rectum				
		Endometrium				
		Pancreas				
		Ovary				
		Bile Duct				
mbIL-15 TCR-T cell Therapy	*KRAS* & *TP53* Hotspot Mutations	Solid Tumors				
Undisclosed Targets & Modalities (hunTR™)	Cancer-specific Somatic Mutations	Cancers with Hotspot Mutations				

ALAUNOS THERAPEUTICS

TCR-T is Superior to Other Cell Therapy Approaches for Solid Tumors

	TCR-T	CAR-T	TIL
Target Intracellular & Extracellular Antigens	✓		✓
Proven Efficacy in Solid Tumors	✓		✓
Defined Target Specificity	✓	✓	
Targets Somatic Neoantigens	✓		✓
Established Transposon-based Gene Transfer	✓	✓	

Table above not based on head-to-head trials

ALAUNOS THERAPEUTICS

A Differentiated TCR-T Program Targeting Solid Tumors

Targeting Hotspot Mutations

Hotspot mutations are ideal targets for defeating cancer

***Sleeping Beauty* Technology**

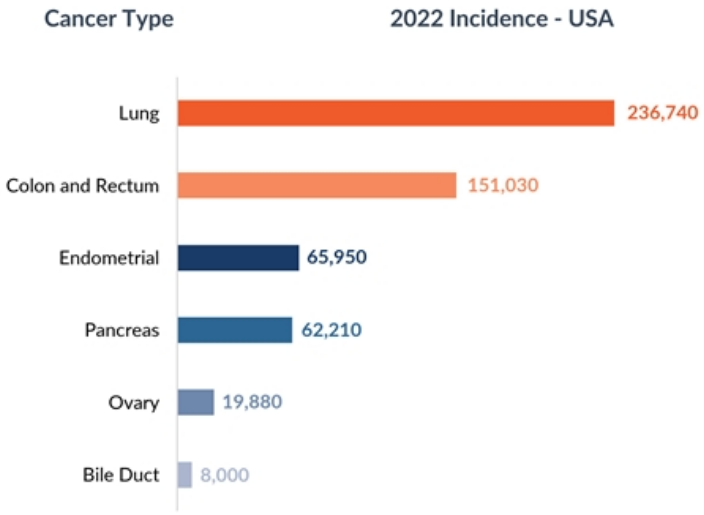
Non-viral transposition technology has favorable safety profile

Rapid, flexible & cost-effective manufacturing

hunTR™ Platform
(human neoantigen T cell Receptor)

Robust discovery engine enables expansion of TCR Library

Our TCR-T Cell Platform Targets Solid Tumors in Large Patient Populations with Unmet Clinical Need

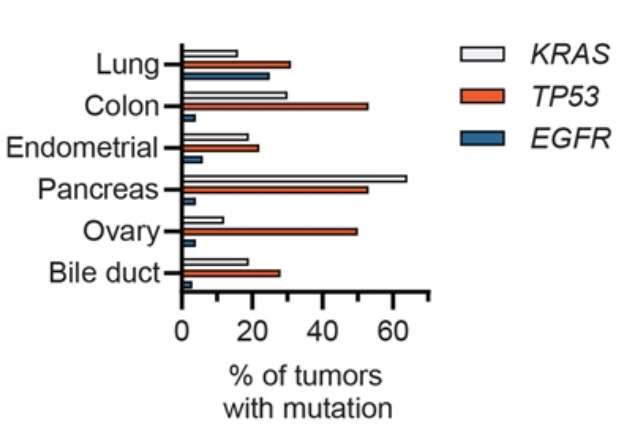


- In the US, 92% of new cancer cases are solid tumors
- 4,804 patients are diagnosed every day with cancerous solid tumor
- 1,548 patients die every day from a solid tumor cancer

Source: https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html
https://www.cancer.org/cancer/bile-duct-cancer/about/key-statistics.html; CA CANCER J CLIN 2021;71:7–33

ALAUNOS THERAPEUTICS

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



High frequency tumor targets, not expressed in normal tissues

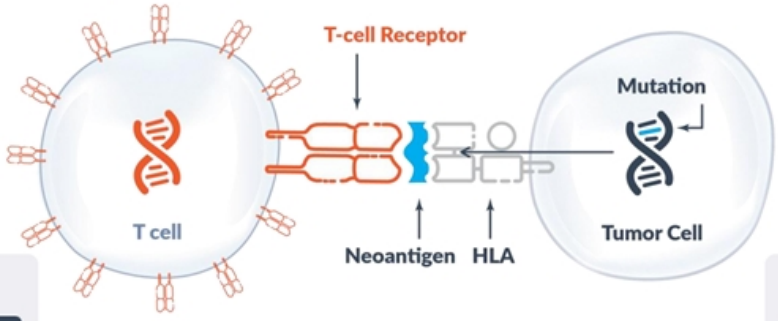
Killer TCR-T cells specific for the mutation without off-tumor toxicity

Unmet clinical need for patients with solid tumors

Source: Catalogue of Somatic Mutations in Cancer (COSMIC) database
https://cancer.sanger.ac.uk/cosmic

ALAUNOS THERAPEUTICS

TCRs Can Give Patients' T Cells a New Ability to Recognize and Kill Tumor Cells with Common Mutations



T-cell Receptors

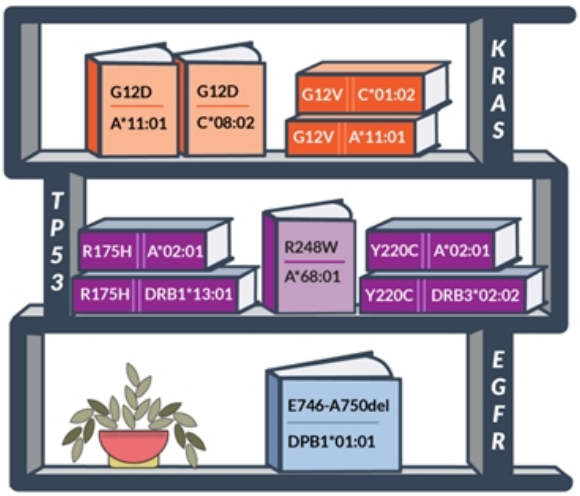
- Naturally occurring
- Highly specific
- Intracellular and extracellular targets

Neoantigens

- Derived from mutations
- Expressed by tumor, not in normal tissues
- Presented on the tumor surface by HLA

ALAUNOS THERAPEUTICS

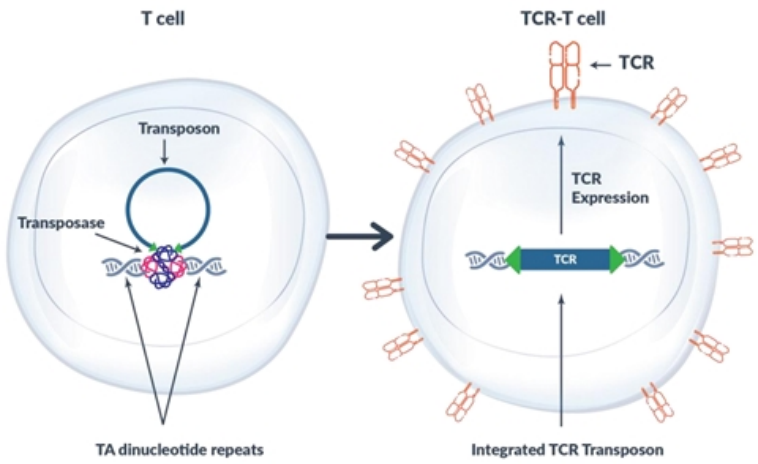
TCR Library Captures High Frequency Mutations and HLA Types



- Common HLAs are represented in our TCR library
- Certain mutations have more than one HLA restriction
- As more TCRs are added to our library, the addressable patient market size will further increase

ALAUNOS THERAPEUTICS

Non-viral *Sleeping Beauty* Platform for Manufacturing TCR-T Cells



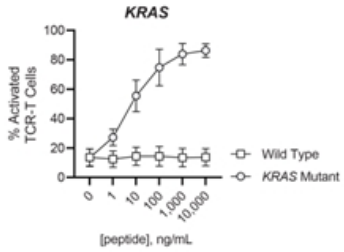
- Efficient integration without the complexity of gene editing or viral approaches
- Rapid, cost-effective manufacturing
- Flexible approach to add TCRs; attractive choice for library
- Platform can accommodate large transgene size
- Process scalable for clinical production

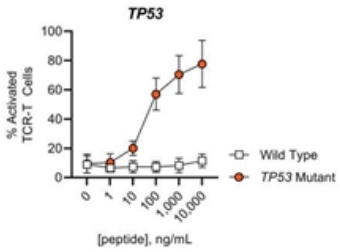
TCR-T Cells Recognize *KRAS*, *TP53*, *EGFR* Mutations and Kill Solid Tumor Cells

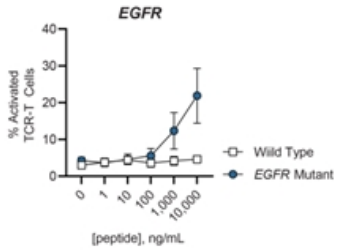
Powerful TCRs:
Naturally-occurring, high avidity TCRs recognize low levels of neoantigens

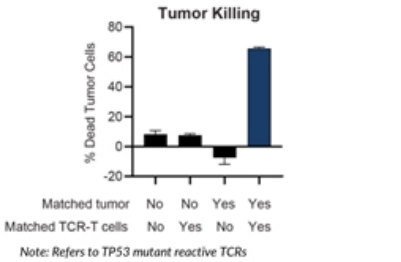
No off-target toxicity observed:
Specificity for the mutation with negligible recognition of the wild type sequences

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





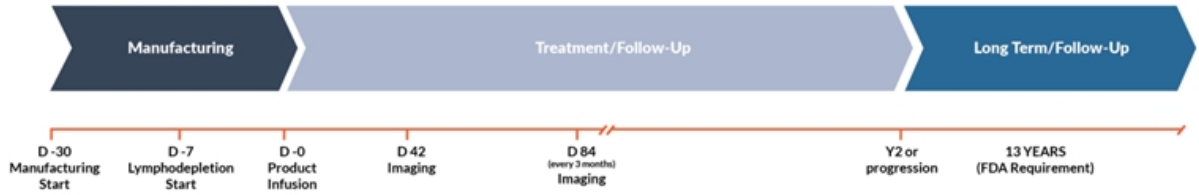




Note: Refers to TP53 mutant reactive TCRs

ALAUNOS THERAPEUTICS

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



- Trial enrolling patients where a TCR matching a neoantigen / HLA pairing is available in our TCR-T library.
- Phase I is a prospective, open-label, dose-escalation study of TCR-T cells in patients with progressive or recurrent solid tumors who have failed standard therapy utilizing a Bayesian optimal interval design (BOIN) with an accelerated dose escalation.
- Patients will be enrolled in one of three dose cohorts.
- Expect to dose first patient in 1H 2022 (NCT05194735).

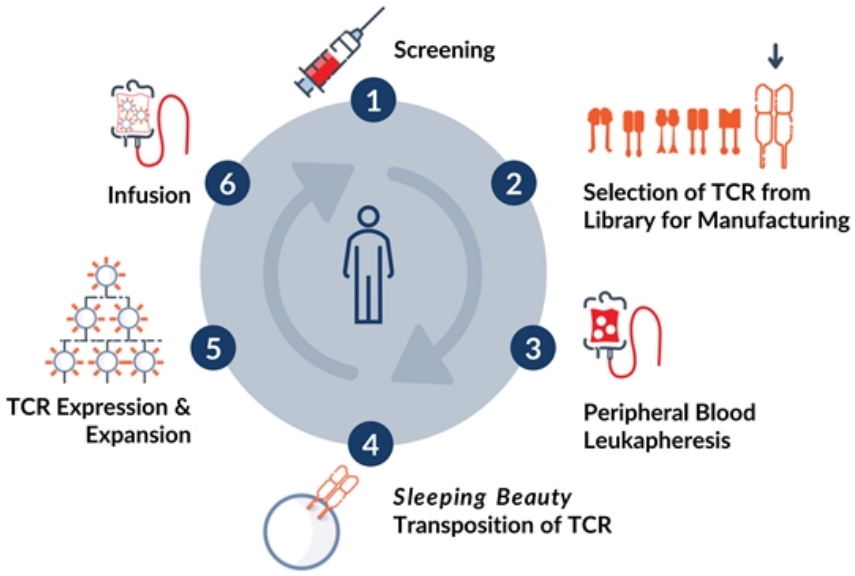
Phase I Objectives:

- Define dose limiting toxicity (DLT) and the maximum tolerated dose (MTD) or recommended phase II dose (RP2D).
- Evaluate the feasibility of TCR-T cell drug product manufacturing.

- Phase II (Dose Expansion) is a prospective, open-label, single-dose portion of the study which is expected to begin once the MTD/RP2D in the Phase I part has been determined.

ALAUNOS THERAPEUTICS

Each Autologous TCR-T Cell Product is Manufactured with a TCR Matched for the Patient's Mutation and HLA Type



ALAUNOS THERAPEUTICS

State of the Art, In-House cGMP Manufacturing Facility Operational

Provides control over clinical manufacturing, including expertise and scheduling

Located in Houston near Texas Medical Center

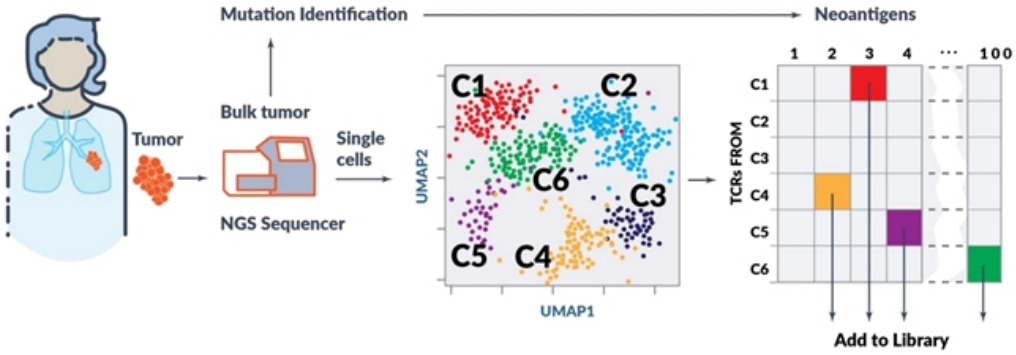
Staffed by highly skilled Alaunos personnel

Will be used for early phase clinical manufacturing

TCR-transposed T cells targeting neoantigens have been grown:

- with high TCR expression
- to clinical dose levels
- with high viability

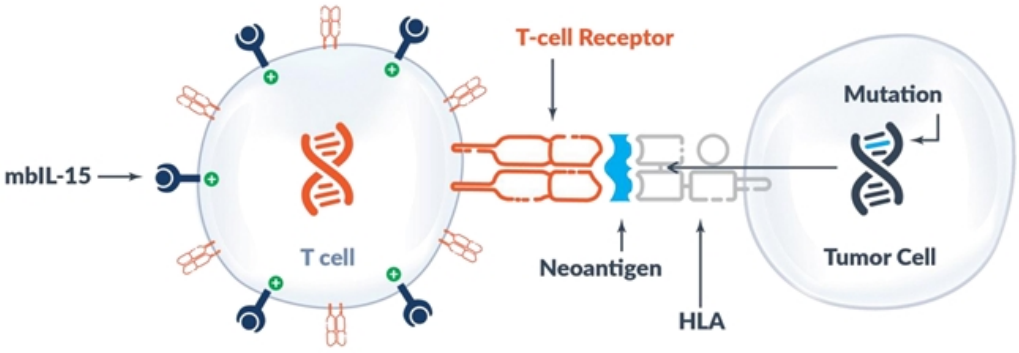
hunTR™ Program Rapidly Expands TCR Library Targeting Hotspot Mutations



- Focus on neoantigens, particularly those arising from hotspot mutations
- Empirical screening of TCRs from CD4+ and CD8+ T cells directly from tumor
- High-throughput TCR screening

ALAUNOS THERAPEUTICS

mbIL-15 Improves the Persistence and Anti-tumor Activity of TCR-T cells in the Tumor Microenvironment (TME)

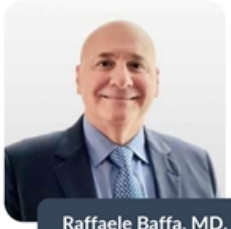


- Pro-survival signaling limits negative signals from the TME
- Stem-cell memory mbIL-15 TCR-T cells regenerate TCR-T cells
- Limit effects of HLA loss by supporting TILs and NK cells
- Potential for TCR-T cell therapy without lymphodepletion

Experienced Management Team

Kevin S. Boyle, Sr.
Chief Executive Officer

Ellee de Groot, PhD
EVP Operations



Raffaele Baffa, MD, PhD
Chief Medical Officer

Melinda Lackey
SVP Legal

Drew Deniger, PhD
VP Research & Development

Mike Wong
VP Finance

Shareholder Value Creation:
A Clinical Stage TCR-T Company Targeting Solid Tumors

Weaponizing the immune system with powerful TCRs to treat solid tumors

Targeting driver mutations using T cells genetically modified with proprietary non-viral *Sleeping Beauty* platform

Vision 2022 – Execution Mindset, Delivering Results

1. Phase 1/2 TCR-T Library Trial Enrolling; FPI anticipated 1H22, interim data expected 2H22
2. Clinical Library of 10 TCRs (*KRAS*, *TP53*, *EGFR*) Targeting Six Solid Tumor Indications
3. Internal cGMP Manufacturing Facility For TCR-T Library Trial
4. Proprietary TCR Discovery Platform, hunTR™, Expanding and Advancing the Pipeline