

**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 26, 2022 (January 25, 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)

ZIOPHARM Oncology, Inc.
(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 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

Effective January 25, 2022, ZIOPHARM Oncology, Inc. changed its name (the "Name Change") to Alaunos Therapeutics, Inc. (the "Company"). The Name Change was effected following approval by the Company's Board of Directors through the filing of a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation. A copy of the Certificate of Amendment is filed as Exhibit 3.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure

On January 26, 2022, representatives of the Company presented slides with a business update. A copy of the presentation is furnished as Exhibit 99.1 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 26, 2022, the Company issued a press release announcing certain corporate and operational updates, including the opening of the Company's Phase 1/2 T-cell receptor T cell therapy (TCR-T) Library trial for enrollment and the Name Change. The press release also announced that the Company's common stock would begin trading under the symbol "TCRT" on The Nasdaq Global Select Market, effective January 27, 2022. 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.

In connection with the Name Change, the Company launched a new corporate website: www.alaunos.com. The Company's investor relations information, including press releases and links to the Company's filings with the Securities and Exchange Commission (the "SEC"), will now be found on this website. The Company's SEC filings and the Company's corporate governance documents, including the charters of the committees of the Company's Board of Directors and Code of Ethics and Business Conduct, are available on this website. Any amendments to or waivers of the Company's Code of Ethics and Business Conduct will be disclosed on this website.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
3.1	Certificate of Amendment, dated January 25, 2022
99.1	Presentation, dated January 2022
99.2	Press release, dated January 26, 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: January 26, 2022

By: /s/ Kevin S. Boyle, Sr.

Name: Kevin S. Boyle, Sr.

Title: Chief Executive Officer

**CERTIFICATE OF AMENDMENT
OF THE
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
ZIOPHARM ONCOLOGY, INC.**

ZIOPHARM Oncology, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. The name of the Corporation is ZIOPHARM Oncology, Inc., formerly known as EasyWeb, Inc. The date of filing of its original Certificate of Incorporation with the Secretary of State was May 16, 2005.

2. This Certificate of Amendment amends the provisions of the Corporation's Amended and Restated Certificate of Incorporation filed with the Secretary of State on April 26, 2006, as amended (the "Certificate of Incorporation").

3. Article 1 of the Certificate of Incorporation is hereby amended and restated to read as follows:

"1. *Name.* The name of the corporation is Alaunos Therapeutics, Inc. (the "Corporation")."

4. This Certificate of Amendment has been duly adopted in accordance with the provisions of Section 242 of the General Corporation Law.

5. All other provisions of the Certificate of Incorporation shall remain in full force and effect.

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IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment to be signed by its Chief Executive Officer this 25th day of January, 2022.

/s/ Kevin S. Boyle, Sr.

Name: Kevin S. Boyle, Sr.

Title: Chief Executive Officer

Attacking Solid Tumors with Novel TCR-T Cell Therapies

| January 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

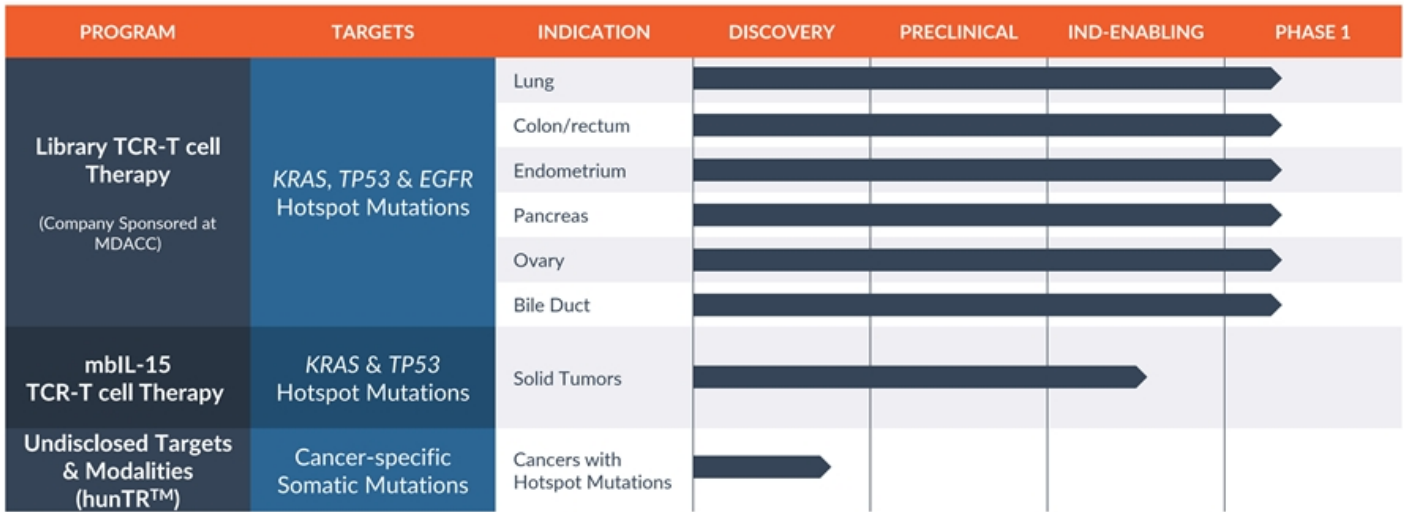
- 1 Phase 1/2 TCR-T Library Trial Enrolling; FPI anticipated 1H22, interim data expected 2H22
- 2 Clinical Library of 10 TCRs (*KRAS*, *TP53*, *EGFR*) Targeting Six Solid Tumor Indications
- 3 Utilize internal cGMP Manufacturing Facility For TCR-T Library Trial
- 4 Proprietary TCR Discovery Platform,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

From Ziopharm to Alaunos:

Focused and Executing on Advancing our Novel TCR-T Platform



TCR-T Platform with Multiple Solid Tumor Programs in Pipeline



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

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

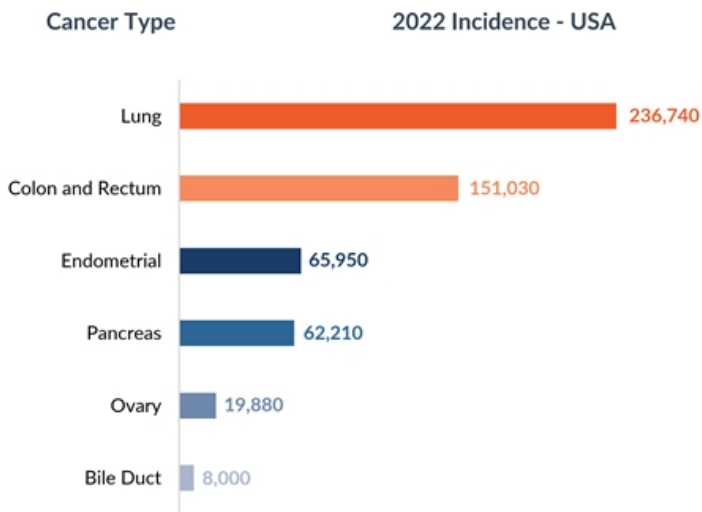
Rapid, flexible & cost-effective manufacturing



hunTR™ Platform (human neoantigen T cell Receptor)

Robust discovery engine enables expansion of TCR Library

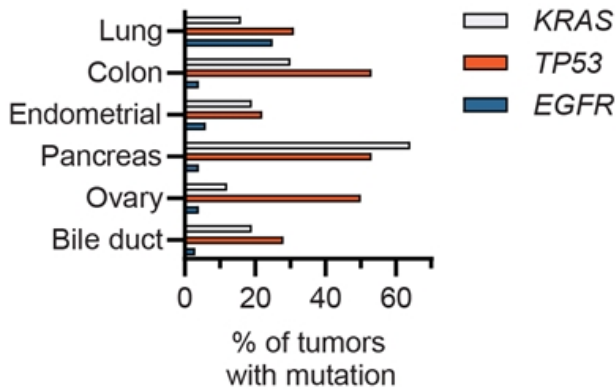
Our TCR-T Cell Platform Targets Solid Tumors in Large Patient Populations with Unmet Clinical Need



- 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

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



High frequency tumor targets, not expressed in normal tissues

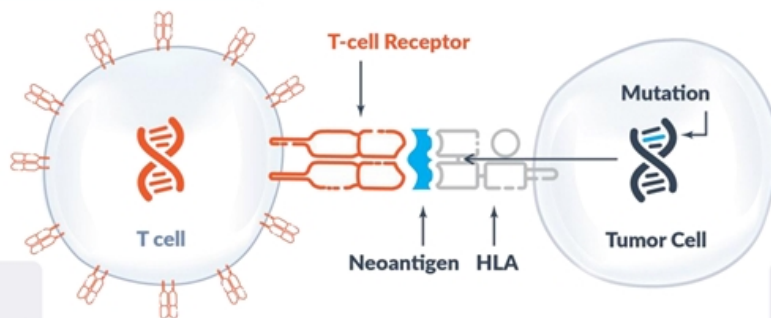


Killer TCR-T cells specific for the mutation without off-tumor toxicity



Unmet clinical need for patients with solid tumors

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

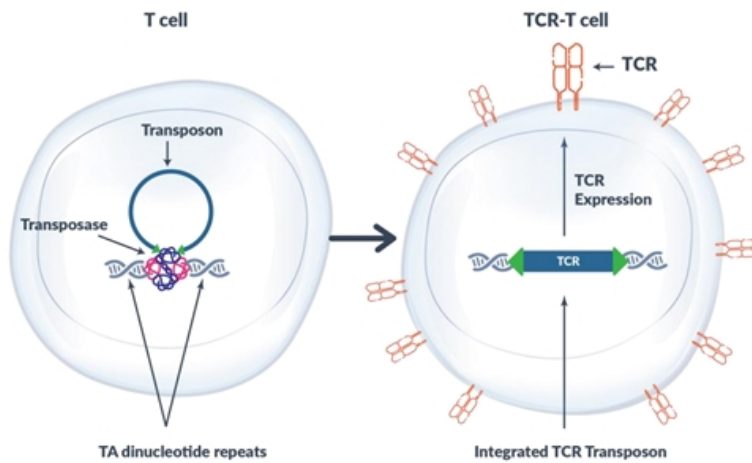
- Derived from mutations
- Expressed by tumor, not in normal tissues
- Presented on the tumor surface by HLA

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

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



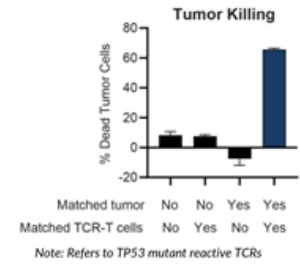
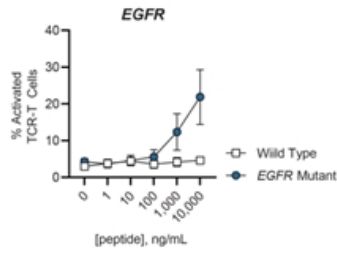
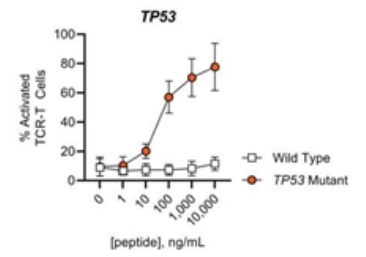
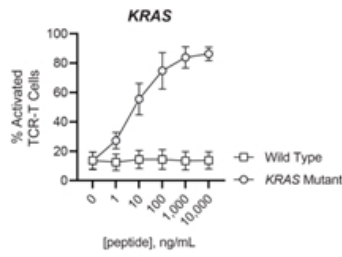
No off-target toxicity observed:

Specificity for the mutation with negligible recognition of the wild type sequences

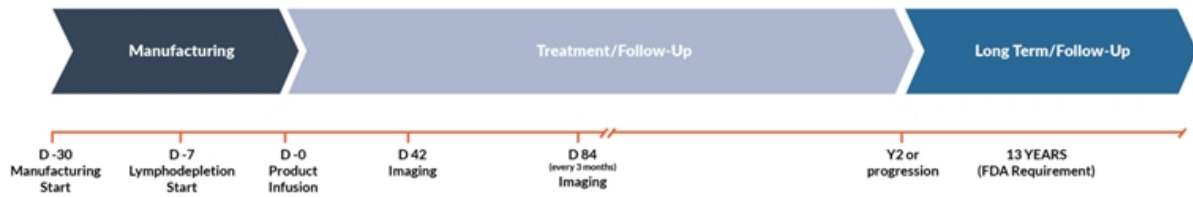


Tumor killing:

Recognition of tumor cells that express mutation and HLA



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



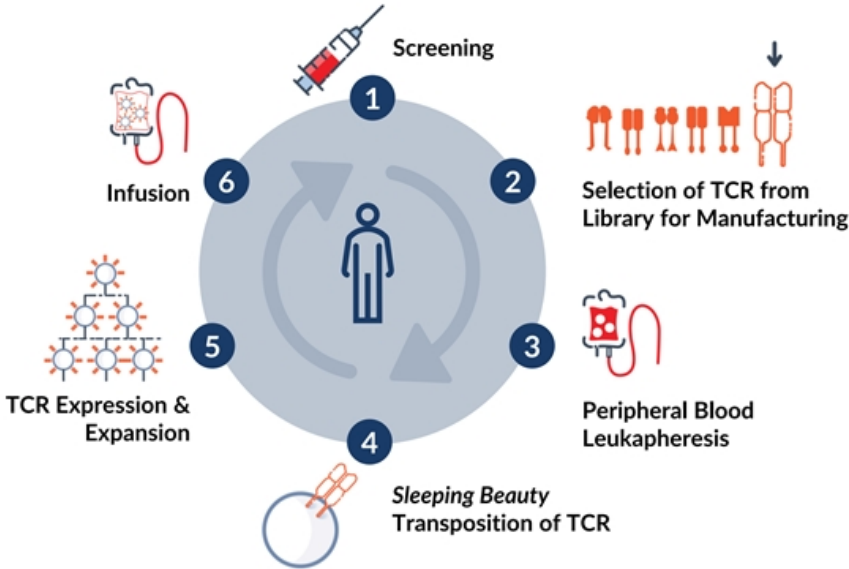
- ✔ Trial enrolling patients where a TCR matching a neoantigen / HLA pairing is available in our TCR-T library.
- ✔ Phase I is a prospective, open-label, dose-escalation study of TCR-T cells in patients with progressive or recurrent solid tumors who have failed standard therapy utilizing a Bayesian optimal 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.

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



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 Alauos personnel



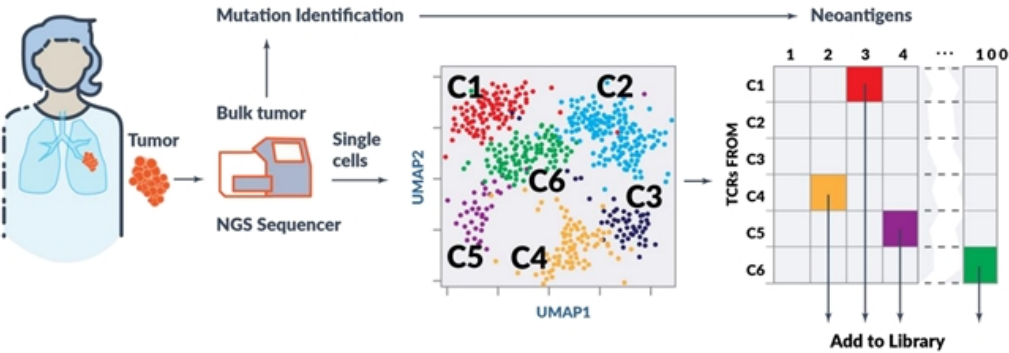
Will be used for early phase clinical manufacturing



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

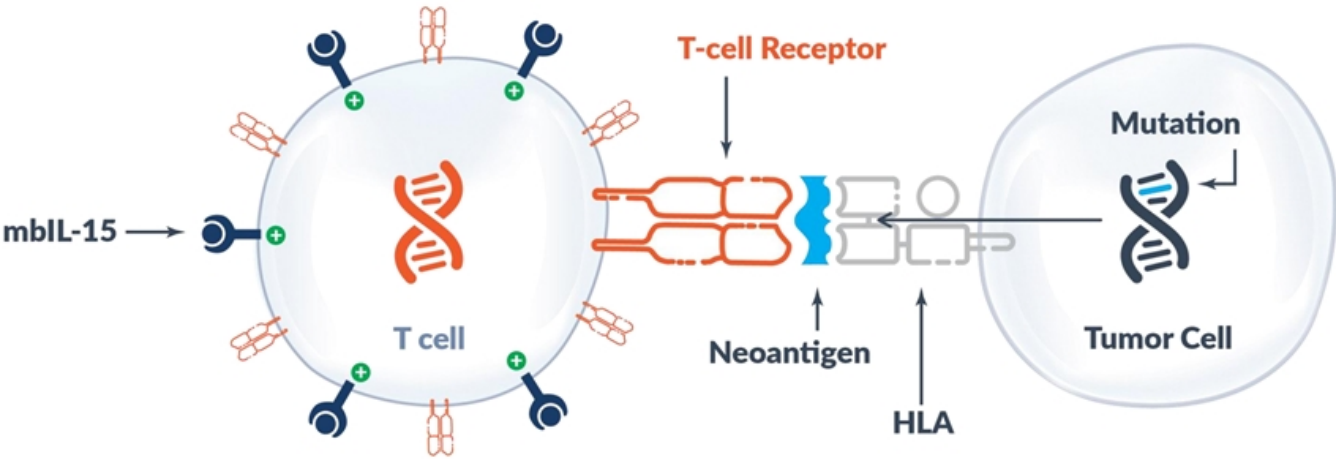


✓ Focus on neoantigens, particularly those arising from hotspot mutations

✓ Empirical screening of TCRs from CD4+ and CD8+ T cells directly from tumor

✓ High-throughput TCR screening

mbIL-15 can be Co-expressed with TCRs



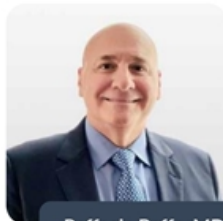
Experienced Management Team



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



Ziopharm Oncology Highlights Operational Progress & Rebrands to Alaunos Therapeutics

- *Phase 1/2 TCR-T Library trial targeting KRAS, TP53 and EGFR mutations across six solid tumor indications is open for enrollment; continue to expect to dose the first patient in 1H 2022*
- *Phase 1/2 IND amended to include four additional TCRs, bringing the total number of evaluable TCRs to 10, further expanding number of eligible patients*
- *In-house cGMP manufacturing facility is operational to support internal clinical development programs*
- *Company changes name to Alaunos Therapeutics reflecting renewed focus*

HOUSTON, January 26, 2022 — Ziopharm Oncology, Inc. (“Ziopharm” or the “Company”) (Nasdaq: ZIOP), a clinical-stage oncology-focused cell therapy company, today highlighted recent operational and corporate updates. The Company also announced that it has changed its name to Alaunos Therapeutics, Inc. (“Alaunos” or the “Company”).

“We are very pleased to announce that our Phase 1/2 TCR-T library trial is now open for enrollment at MD Anderson Cancer Center. This first of its kind study, enabled by our versatile non-viral *Sleeping Beauty* technology, will allow us to efficiently target six solid tumor indications within this single clinical trial. In addition, our R&D efforts continue to bear fruit and we amended our IND to include four additional TCRs to the study. This further increases the number of eligible patients who could benefit from our therapies, and we look forward to dosing the first patient in this study within the first half of this year. Lastly, to support our clinical development, we have successfully opened our cGMP manufacturing facility and we are now able to manufacture our autologous cell therapy products in-house,” commented Kevin S. Boyle, Sr., Chief Executive Officer.

“Over the course of 2022, the team will continue to work diligently with an execution mindset to deliver results. In addition to translating groundbreaking science into meaningful clinical progress we will work to advance our membrane bound IL-15 program with IND enabling studies. Our name change to Alaunos Therapeutics reflects the completion of our transition to a TCR-T focused company and embodies our mission of developing novel therapies for cancer patients,” concluded Mr. Boyle.

Operational Updates

- **Phase 1/2 TCR-T Library Program Open for Enrollment:** Alaunos’ phase 1/2 clinical trial is evaluating library TCR-T shared hotspot neoantigens using the Company’s *Sleeping Beauty* transposon/transposase technology. The Company added four additional T-cell receptors (TCRs) to its library, further increasing the number of eligible patients for the clinical trial. The study being conducted

at MD Anderson Cancer Center is an open label, dose escalation study that will enroll patients who have a matched HLA and hotspot mutation that is targeted by one of the 10 TCRs from the Alaunos library. The trial will evaluate 10 unique TCRs targeting *KRAS*, *TP53* and *EGFR* mutations in patients across a broad range of solid tumors that include non-small cell lung, colorectal, endometrial, pancreatic, ovarian, and bile duct cancers, all in a single trial. The Phase 1 primary endpoint is maximum tolerated dose or recommended phase 2 dose. The Company expects to dose the first patient in the first half of 2022 and to provide an interim data update later this year. Additional information about the study is available at www.clinicaltrials.gov using the identifier: NCT05194735.

- **In-House cGMP Manufacturing Facility Operational:** Alaunos completed the qualification of its state-of-the-art good manufacturing practice (cGMP) TCR manufacturing facility near the Texas Medical Center in Houston. The facility is staffed by Alaunos personnel and is fully operational for the manufacture and release of clinical product.
- **hunTR™ (human neoantigen T-cell Receptor) Platform for TCR Discovery:** Alaunos' TCR hunting process, hunTR™, enables the rapid identification of new and proprietary TCRs from CD4+ and CD8+ T cells to further expand the Company's growing TCR-T library. The platform can evaluate thousands of single T cells simultaneously using state-of-the-art bioinformatics and next generation sequencing to identify TCRs specific for neoantigens that arise from hotspot mutations. The proprietary high-throughput TCR screening process permits rapid functional validation of TCRs. Newly discovered neoantigen-specific TCRs will then undergo further development required to potentially qualify the TCR for inclusion in the Company's TCR library and clinical evaluation.

Corporate Updates

- **Name Change to Alaunos Therapeutics, Inc.:** The name Alaunos originates from the Celtic mythological god of healing, reflecting the Company's commitment to developing therapies for cancer patients. The Company will trade on The Nasdaq Stock Market under the new ticker symbol "TCRT", to be effective at market open on January 27, 2022. In conjunction with the corporate name change, the Company has launched a new website, www.alaunos.com, which contains information about the Company and its innovative TCR-T platform.
- **Closure of Boston, MA Location:** To streamline operations, the Company has closed its Boston office. Alaunos will be headquartered in Houston.

About Alaunos Therapeutics, Inc.

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 platform and its unique cancer mutation hotspot TCR library, targeting common tumor-related 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

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“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 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. 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:

Alex Lobo
Stern Investor Relations
Alex.lobos@sternir.com