

**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 14, 2021**

**ZIOPHARM Oncology, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-33038**  
(Commission  
File Number)

**84-1475642**  
(IRS Employer  
Identification No.)

**One First Avenue, Parris Building 34, Navy Yard Plaza**  
**Boston, Massachusetts**  
(Address of Principal Executive Offices)

**02129**  
(Zip Code)

**(617) 259-1970**  
(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 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
<b>Common Stock, par value \$0.001 per share</b>	<b>ZIOP</b>	<b>The Nasdaq Stock Market LLC</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act (17 CFR 230.405) or Rule 12b-2 of the Exchange Act (17 CFR 240.12b-2).

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 14, 2021, Ziopharm Oncology, Inc. (the “Company”) conducted a presentation at the 39th Annual J.P. Morgan Healthcare Conference. In addition, on January 14, 2021, the Company issued a press release announcing that James Huang has been elected the Chairman of the Company’s Board of Directors (the “Board”) and Heidi Hagen has been elected the Lead Independent Director of the Board.

A copy of the presentation and press release are furnished as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K, respectively. The information in this Item 7.01 and Exhibits 99.1 and 99.2 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Presentation of Ziopharm Oncology, Inc. dated January 14, 2021.</a>
99.2	<a href="#">Press Release of Ziopharm Oncology, Inc. dated January 14, 2021.</a>
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.

**ZIOPHARM ONCOLOGY, INC.**

Date: January 14, 2021

By: /s/ Robert Hadfield  
Name: Robert Hadfield  
Title: General Counsel and Secretary



**Ziopharm**  
ONCOLOGY

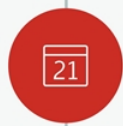
J.P. Morgan 39<sup>th</sup> Annual Healthcare Conference  
January 14, 2021



# Forward Looking Statements

This presentation contains certain forward-looking information about Ziopharm Oncology, Inc. that is intended to be covered by the safe harbor for "forward-looking statements" provided by 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," and "believes." These statements include, but are not limited to, statements regarding our business and strategic plans, the availability of cash resources, the progress and timing of our research and development programs, including the anticipated dates for the FDA clearance, initiation, patient dosing and data readouts of our clinical trials, the potential market and treatment opportunity of our products, expectations regarding partnership opportunities for our programs and the number of patients in our clinical trials. Although Ziopharm's management team believes 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 Ziopharm, 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 our operating plans that may impact our cash expenditures; the uncertainties inherent in research and development, future clinical data and analysis, including whether any of Ziopharm's 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. FDA or equivalent foreign regulatory agencies and for which indication; the strength and enforceability of Ziopharm's intellectual property rights; 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 Ziopharm, including those risks and uncertainties listed in Ziopharm's quarterly report on Form 10-Q for the three months ended September 30, 2020 filed by Ziopharm with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date of the presentation, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

# Agenda



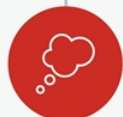
Where We Are  
Entering The Year



Approach For Our CAR-T  
And IL-12 Programs

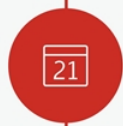


TCR-T Program: Our Top  
Priority And Opportunity



2021 Expectations

# Agenda



Where We Are  
Entering The Year



Approach For Our CAR-T  
And IL-12 Programs



TCR-T Program: Our Top  
Priority And Opportunity



2021 Expectations

Evolved strategy and disciplined capital allocation

## Mission

We develop innovative T cell-based therapies for the treatment of solid tumors, treating cancer on time, one cell at a time

# Ziopharm Oncology Today

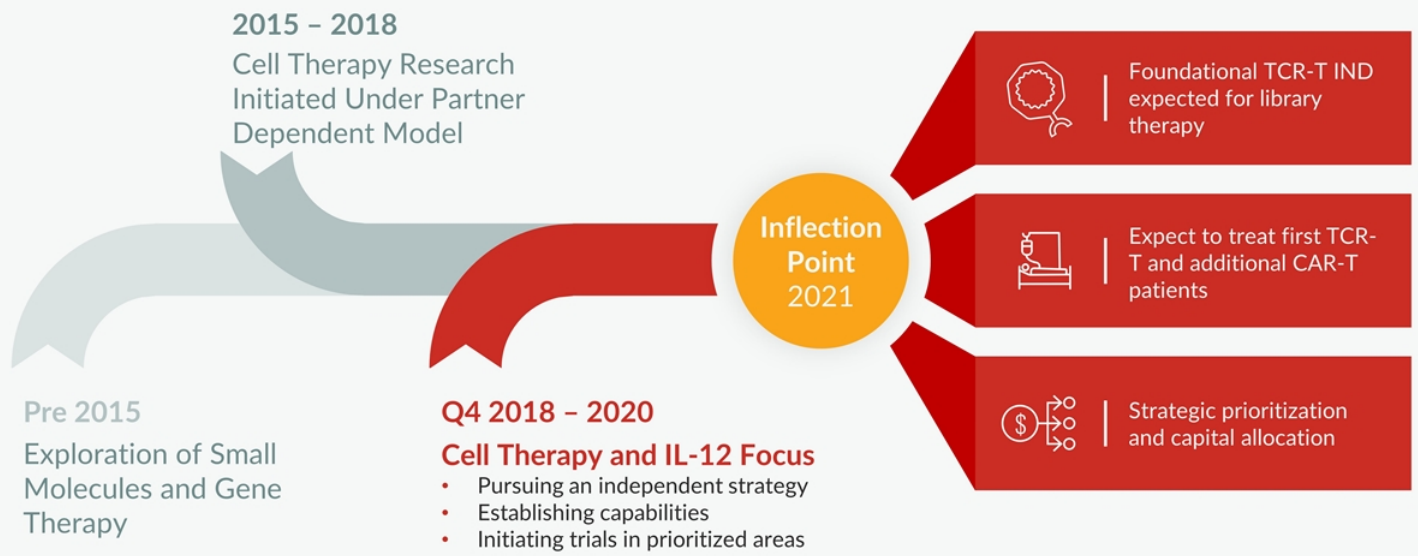
## Long-Term Vision

Distinctive commercial and clinical portfolio of immunotherapies transforming patient lives, supported by a growing body of compelling data

Well positioned with distinctive platforms in clinic



# 2021 is a Key Inflection Point for the Company



# Addressing Shareholder Feedback is Critically Important

## Shareholder Feedback

- 01 Dissatisfaction with engagement and Board/management flux
- 02 Concerns regarding the capital requirements of carrying three platforms forward
- 03 Delays in program progress (e.g., NCI TCR-T Personalized Phase 2, CAR-T)
- 04 Share price erosion

## How we are Addressing

- Refreshing Board with active shareholder participation and input; renewed IR approach
- Strategically prioritizing our capital allocation expenditure and making the tough decisions
- Controlling our own destiny through building operational capabilities and infrastructure
- Unlocking under-appreciated value through focus, transparency (e.g., R&D / Investor Day in Q1) and execution

## We Have the Core Technology and Infrastructure to be Leaders in Cell Therapy

- 01 Pioneers in non-viral gene transfer
- 02 Cytokine biology expertise
- 03 Eden Biocell advancing CAR-T in Asia
- 04 Building momentum in TCR-T clinical programs
- 05 Leadership and innovation in T-cell immunobiology
- 06 Establishing infrastructure and capabilities for clinical programs
- 07 Strong SAB and established partnership network bring external strength

# 2021 is a Year of Disciplined Strategic Focus

Strategy entails transparent prioritization and directed capital allocation

## Strategic Filters

- 01 Our distinct capabilities
- 02 Balance of de-risked feasibility and innovation
- 03 Direct line of sight to patient data and unmet need
- 04 Assessment of resource and capital constraints

## Strategic Positioning



TCR-T Programs: Advance clinical program for library as top internal priority (and expand library); plan for personalized / next gen program(s); leverage NCI where possible



CD19 CAR-T Programs: Cost effectively advance program to generate clinical data. Evaluate partnership opportunities for future development and commercialization. Evaluate cross-over potential of CAR-T technology to the TCR program



Controlled IL-12 Program: Seek partner(s) that can optimize the potential of the asset for patients and monetize / return value to Ziopharm shareholders

# Agenda



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TCR-T Program: Our Top  
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2021 Expectations

# Neoantigens are the Blueprint for Targeting Solid Tumors

Can be addressed by “off-the-shelf” library or personalized approaches

## The Right Targets

All cancer cells contain mutated genes which may be translated into neoantigens and presented to T cells through the natural immune system processes. There is no expression on normal tissues of the mutated genes

## Clinical Foundation

Established, metastatic tumors have been eliminated by infusion of neoantigen-reactive T cells resulting in objective clinical benefit

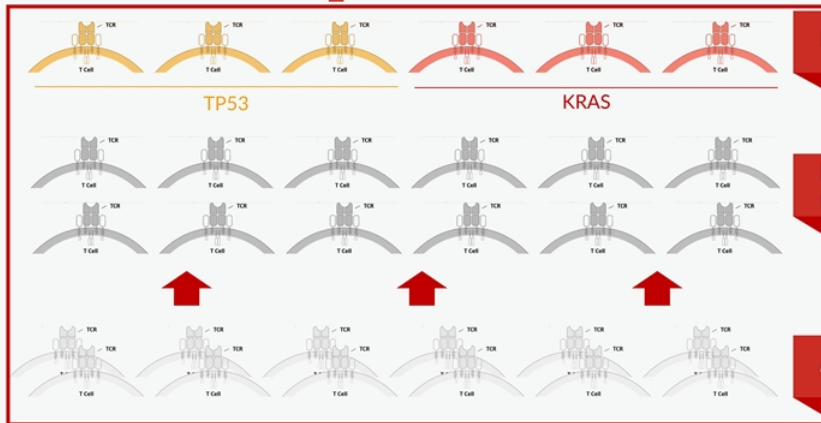
## Treatment Opportunity

We believe over half of all cancer patients could potentially be treated by this type of immunotherapy meaning 7M+ patients suffering today could benefit in the US alone (plus 700-800K new patients every year), with potential for global expansion



# TCR-Based Immunotherapies Can Potentially Address Significant Patient Need Across Broad Range of Solid Tumors

## Expanding Off-the-Shelf TCR Library – Q1 2021 IND On Track



Initially, up to six unique TCR/HLA TCRs in IND

- Candidate TCRs through ongoing vetting process
- 3 each against TP53 and KRAS hotspots
- Tumor types: Lung, Cholangiocarcinoma, Pancreas, Colorectal, Ovarian

Existing library includes 30+ TCRs, targeting 18 unique mutation/HLA combinations (KRAS, TP53, EGFR)

- Covers ~5-6% of epithelial cancers\*
- Translates to ~75-90K new potential patients annually in US (based on incidence of 1.5M per year)
- Potential to bring on additional TCRs through one or more amendments to IND

Active Research and Partnerships to Grow TCR Library

## Personalized TCR-T Approach – Increased Complexity and Broader Applicability

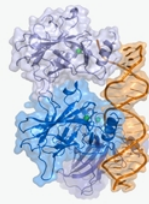


Potential to treat half or more of the ~1.6M annual (US) new cases of cancer

# Pan-Cancer Neoantigen-Specific TCRs Expressed via *Sleeping Beauty* Transposition Lead to Tumor Cell Lysis

TP53

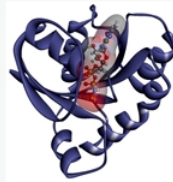
Among the most mutated genes in human cancers  
Functions as a transcription factor to regulate cell division and stabilize the genome



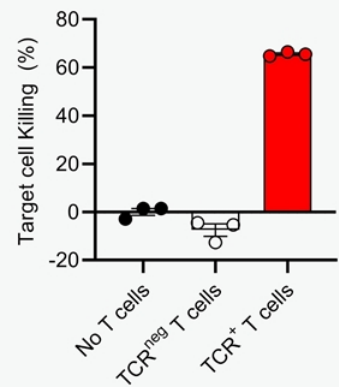
KRAS

KRAS mutations are validated clinical targets

Functions to relay signals that promote cell proliferation, cell differentiation, or cell survival



T cells expressing introduced TCR are specifically activated and kill tumor cells



Source: Internal Unpublished Research

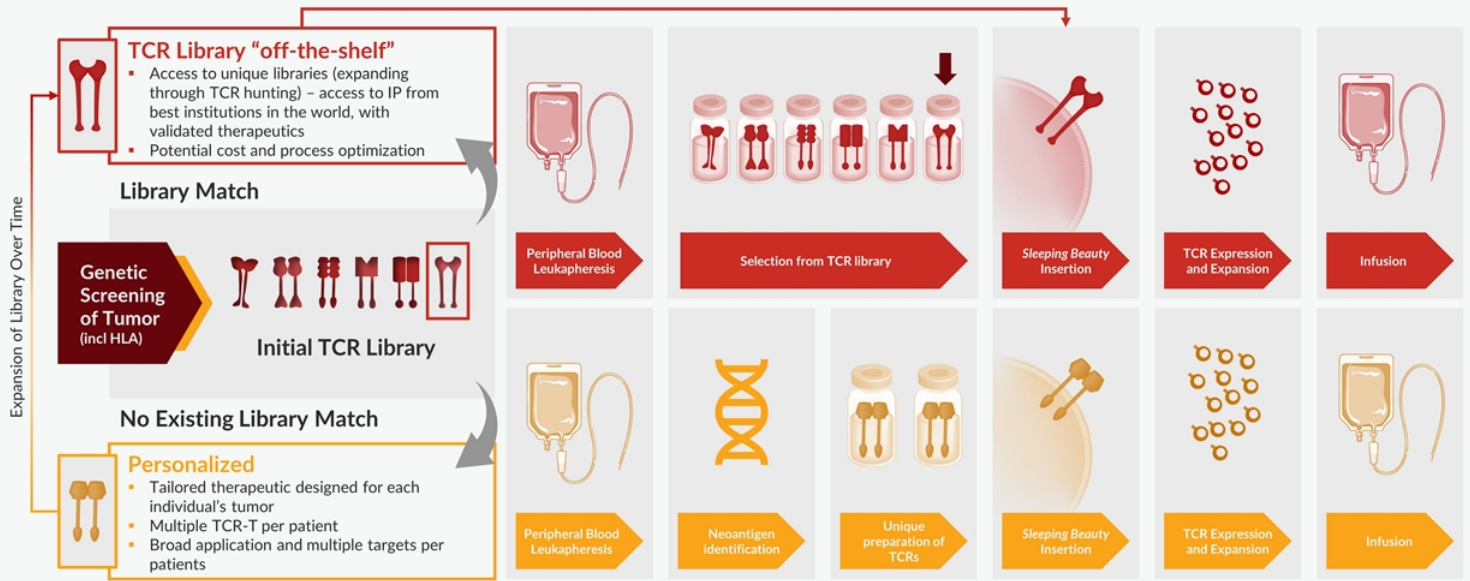
Images: NCI and Wikipedia.org



# Library "Off-the-shelf" and Personalized Cell Therapies

## Diagnostic Pathway

## Treatment Pathway



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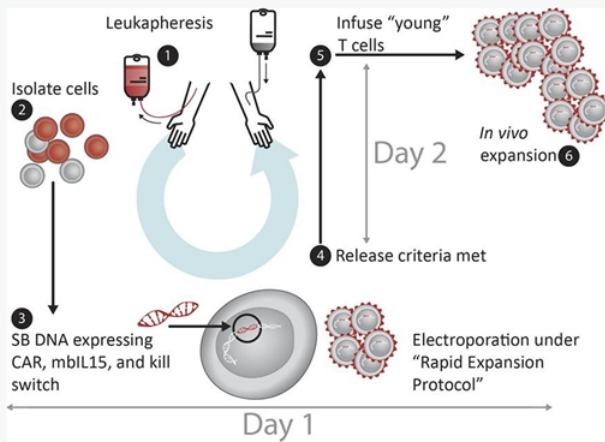
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# CAR-T Innovation: Rapid Personalized Manufacturing (RPM)

## Addressing Cost And Complexity Limiting The Commercialization Of Existing CAR-T



- Uses *Sleeping Beauty* non-viral system
- Local, very rapid, simplified, scalable manufacturing
- Genetic modification of resting T cells with CAR and membrane-bound IL-15 (mblL15) to preserve "young" state
- mblL15 may avoid lymphodepletion
- Administering low numbers of T cells to expand in the body may avoid cytokine release syndrome
- Rapid manufacture: Can be infused day after gene transfer without the need to ex vivo expand cells

# CD19 CAR Rapid Personalized Manufacturing (RPM) – Clinical Programs

A solution to cost and complexity of commercial CAR-T today with one continuous program

## Phase 1 Trial Initiated To Evaluate Allogeneic CD19 CAR-T

- Investigational treatment for patients with CD19+ leukemias and lymphomas who have relapsed after allogeneic bone marrow transplantation
- Strategic purpose to validate Ziopharm's RPM technology, potential commercial opportunity
- Infuse as soon as day after gene transfer
- Trial to be conducted at MD Anderson; Initiation announced in July 2020

## Ziopharm & Eden BioCell pursuing autologous CD19 CAR-T

- 50-50 joint venture with TriArm Therapeutics
- Taiwan: Eden BioCell IND cleared in Q4 2020 for Phase 1 trial
- Mainland China: Infusion of several patients with encouraging data



Eden BioCell

# CD19 CAR Rapid Personalized Manufacturing (RPM) – Status Summary



Eden BioCell

Partnering with Tri-Arm Therapeutics via our JV Eden Biocell

■ Compassionate Use  
■ Investigator Initiated



Female

52 years old

FL

Two prior lines of therapy

Treated in Jul-2020

Appears well tolerated  
No serious CRS



Male

49 years old

MCL

Four prior lines of therapy

Treated in Aug-2020

Appears well tolerated  
No serious CRS



Male

62 years old

DLBCL

Seven prior lines of therapy

Treated in Aug-2020

Appears well tolerated  
No serious CRS



Male

55 years old

ALL

Two prior lines of therapy

Treated in Sep-2020

Appears well tolerated  
No serious CRS



Male

56 years old

DLBCL

Three prior lines of therapy

Treated in Dec-2020

Appears well tolerated  
No serious CRS

Early indications of strong *in vivo* T-cell proliferation

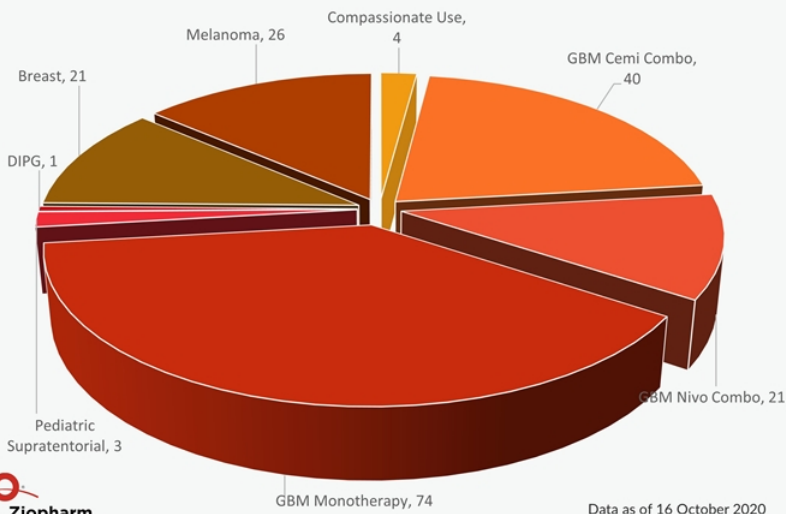
Encouraging for potential application in TCR-T efforts

Patient monitoring and follow up ongoing; clinical safety and efficacy to be determined

# Development Summary For Controlled IL-12

A late-stage immuno-oncology platform with >2,000+ doses of veledimex administered in >175 patients

## Clinical Trial Enrollment



- 01 Mechanism of action enables treatment across many solid tumors as monotherapy or in combination  
Turning cold tumors hot improves tumor microenvironment for other treatments
- 02 Well-tolerated with no drug-related deaths
- 03 rGBM trials have demonstrated clinical benefit (mOS of 16+ months and MRI responses)
- 04 Trials in melanoma and breast cancer established both local and systemic (abscopal) anti-tumor effects
- 05 Injection into the pons was performed safely with no significant adverse events
- 06 Key clinical data read-out from ongoing trials in 2021

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# Disciplined Capital Allocation Directed By Strategic Prioritization

## Financial Snapshot

\$135.5 million in cash and cash equivalents as of 9/30/20

\$11.4 million at MD Anderson from prepayment for programs to be conducted by the Company as of 9/30/20

Sufficient to fund planned operations and execute our strategy into mid-2022

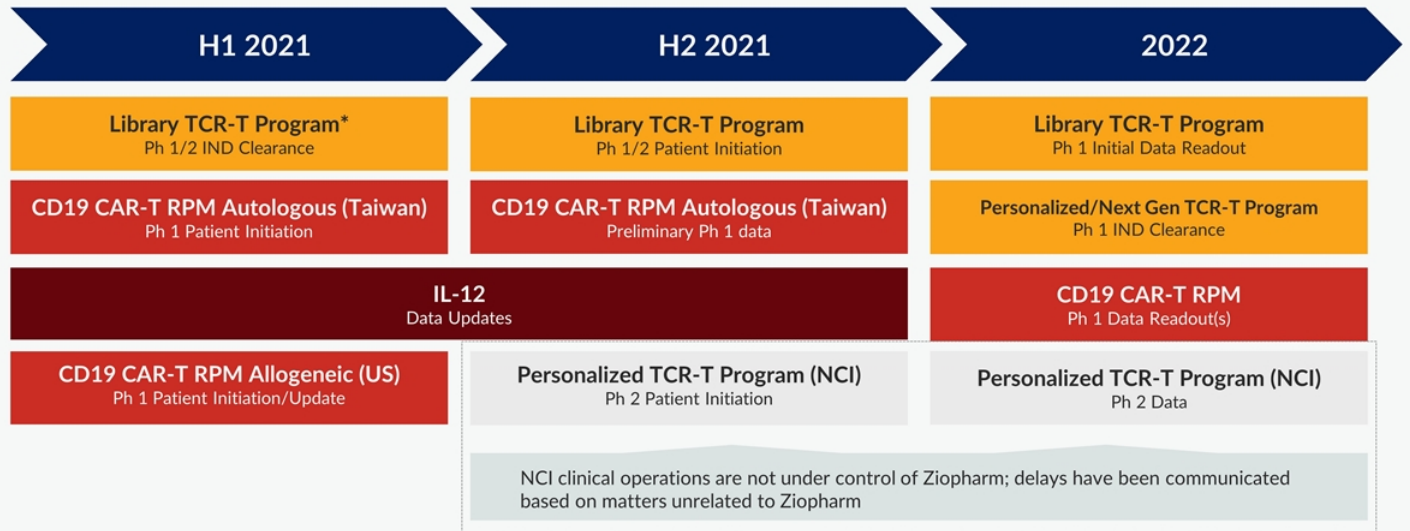
Seeking avenues to **slow cash burn and identify sources of non-dilutive capital** enabled by clear strategic focus

## Capital Allocation Priorities

- 01 TCR-T program advancement with initial focus on ZIOP library clinical study
  - Continued buildout of operational capabilities (Houston)
  - Operationalizing clinical program
  - Hunting for additional TCRs
- 02 CAR-T resourcing to demonstrate initial clinical benefit of RPM
  - Support Eden Biocell Asia clinical program (CD19)
- 03 Return value to company for IL-12 innovation and find right partner to take the program into registrational studies



# Upcoming Clinical Milestones



# 2021 Snapshot of Priorities

IND in Q1 2021 for Ziopharm's TCR-T Library trial to be initially undertaken at MD Anderson; First patient expected in H2

Increase investor outreach;  
Recruitment of additional executive leadership

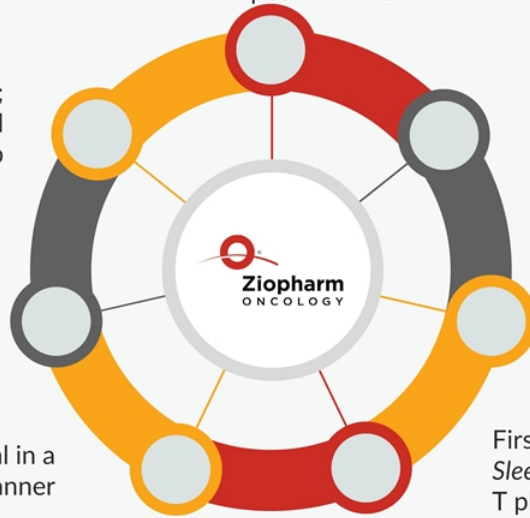
Expect to treat patients and generate RPM CD19 CAR-T Patient Data

Seek best path forward for advancing the IL-12 program

Host R&D Day with management, Steven Rosenberg, Carl June and others in Q1

Utilize and raise capital in a disciplined, strategic manner

First patient expected to be dosed in *Sleeping Beauty* NCI-led Personalized TCR-T phase 2 in H2





**Ziopharm Oncology Announces Election of James Huang as Chairman of the Board of Directors**

*– Mr. Huang is a veteran industry entrepreneur with 20+ years founding and funding biotech innovation –*

*– Heidi Hagen elected Lead Independent Director –*

**Boston, January 14, 2021** — Ziopharm Oncology, Inc. (“Ziopharm” or “the Company”) (Nasdaq:ZIOP) today announced the election of James Huang as Chairman of the Board of Directors (the “Board”), effective immediately.

Mr. Huang has served on the Board since July 2020 and is currently a Managing Partner at Kleiner Perkins Caufield & Byers (KPCB) China. He has founded and financed several innovative life sciences companies, including GenScript, Legend Biotech and Zai Lab. He is also Founding Partner of Panacea Venture, which formed TriArm Therapeutics, the funding partner for Ziopharm’s joint venture, Eden BioCell.

“I am delighted to take on this additional role at Ziopharm and work closely with Laurence to help deliver the company’s transformational CAR-T and TCR technologies to patients”, said Mr. Huang. “I firmly believe the company is in an excellent position, and I look forward to supporting and guiding the efforts of the company to execute on its strategy as Board Chairman.”

Laurence Cooper, M.D., Ph.D., Chief Executive Officer and member of the Board of Directors of Ziopharm, said, “We are pleased to have secured James as our Chairman. James has a stellar track record of supporting and delivering innovation in our space. On behalf of the management team and entire Ziopharm organization, we look forward to James’ leadership of the Board.”

The Company also announced today the election of Heidi Hagen to the position of Lead Independent Director, effective immediately. Ms. Hagen has served on the Board since June 2019.

Ms. Hagen is Co-Founder of Vineti, a cloud-based software platform company that addresses challenges in data management from order through cell collection, manufacturing, and delivery of personalized treatments such as cell and gene therapies and cancer vaccines. She has extensive experience in operations management and commercializing innovative technologies.

The election of Mr. Huang as Chairman of the Board and the election of Ms. Hagen as Lead Independent Director were both supported by unanimous votes of the entire Board of Directors.

#### **James Huang Biography**

James Huang joined KPCB China as a Managing Partner in 2011 and focused on the firm's life sciences practice. Prior to joining KPCB, he was a Managing Partner at Vivo Ventures, a venture capital firm specializing in life sciences investments. While at Vivo, he led numerous investments in China. Prior to joining Vivo in 2007, Mr. Huang was President of Anesiva, a biopharmaceutical company focused on pain-management treatments.

During his 20-year career in the pharmaceutical and biotech industry, Mr. Huang held senior roles in business development, sales, marketing and R&D with Tularik Inc. (acquired by Amgen), GlaxoSmithKline LLC, Bristol-Myers Squibb and ALZA Corp (acquired by Johnson & Johnson). Mr. Huang also built GenScript, including Legend Biotech from a small U.S. venture backed company into a revenue-generating company with a multi-billion valuation on the Hong Kong Stock Exchange and Nasdaq. Mr. Huang received an MBA from the Stanford Graduate School of Business and a BS degree in chemical engineering from the University of California, Berkeley.

#### **About Ziopharm Oncology, Inc.**

Ziopharm is developing non-viral and cytokine-driven cell and gene therapies that weaponize the body's immune system to treat the millions of people globally diagnosed with cancer each year. With its multiplatform approach, Ziopharm is at the forefront of immuno-oncology. Ziopharm's pipeline is built for commercially scalable, cost effective T-cell receptor T-cell therapies based on its non-viral *Sleeping Beauty* gene transfer platform, a precisely controlled IL-12 gene therapy, and rapidly manufactured *Sleeping Beauty*-enabled CD19-specific CAR-T program. The Company has clinical and strategic collaborations with the National Cancer Institute, The University of Texas MD Anderson Cancer Center and Regeneron Pharmaceuticals. For more information, please visit [www.ziopharm.com](http://www.ziopharm.com).

#### **Forward-Looking Statements Disclaimer**

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