#### **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 6, 2019

#### **ZIOPHARM Oncology, Inc.**

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)

001-33038 (Com ission 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)).

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  $\square$ 

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.  $\Box$ 

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 6, 2019, the Board of Directors (the "Board") of Ziopharm Oncology, Inc. (the "Company") awarded a bonus under the Company's annual performance bonus plan to Laurence Cooper, M.D., Ph.D., the Company's Chief Executive Officer, for the year ended December 31, 2018. In lieu of cash, Dr. Cooper and the Company agreed that Dr. Cooper would receive shares of the Company's common stock with an aggregate fair market value on the date of grant equal to the amount of the bonus award. In accordance with this decision, the Board awarded Dr. Cooper 446,428 shares of the Company's common stock.

In addition, the Board approved an increase of Dr. Cooper's annual base salary to \$573,000, granted Dr. Cooper 337,266 shares of restricted common stock that vest in equal annual installments over three years, and granted Dr. Cooper an option to purchase 531,813 shares of common stock with an exercise price of \$2.24 per share that vests in equal quarterly installments over three years.

#### Item 7.01 Regulation FD Disclosure.

On January 10, 2019, the Company conducted an investor presentation at the 37th Annual J.P. Morgan Healthcare Conference in San Francisco, California.

A copy of the investor presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information in this Item 7.01 and Exhibit 99.1 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.

Description

(d) Exhibits

Exhibit No.

99.1 Presentation of Ziopharm Oncology, Inc. dated January 10, 2019.

#### 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.

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

Date: January 10, 2019



### **Forward Looking Statement**

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 the Company's business and strategic plans, the availability of cash resources, and the progress and timing of the development of Ziopharm's research and development programs, including the timing for the initiation and completion of its 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 quarter ended September 30, 2018 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.



#### **Transformed Ziopharm**

To deliver endto-end and scalable TCR-T cell therapy to treat solid tumors To solve the current commercial limitations of cost and scalability of approved CAR-T To harness the power of IL-12 as a drug to address difficultto-treat solid tumors with precision

Ziopharm

### **Ziopharm: Summary and Vision**

### 4Q2018 Accomplishments

- Redefined license agreement with Intrexon and Precigen in October 2018
- Eliminated \$157M of preferred stock issued to Intrexon
- Raised \$50M from existing investors
- No debt, funded to achieve milestones into 2Q2020
- Regeneron collaboration for Controlled IL-12
- Formation of Eden BioCell to expand CD19 CAR-T business to Greater China



#### 2019 and beyond

- Executional excellence
- All programs in clinic in 2019
  5 clinical trials
- In-house capabilities: Expanding laboratory and manufacturing in Houston

#### **Strong Partnerships in Place**





# Sleeping Beauty TCR-T Program

T cells genetically modified to express neoantigen-specific TCRs represent the best opportunity for targeting metastatic solid tumors

- The best TCRs are unique for each patient
- T cells with multiple specificities (multiple TCRs) are required to prevent relapse



## **Sleeping Beauty Scalability**

Solves the manufacturing challenge of targeting neoantigens

#### <u>Problem:</u> 1 patient may need treatment with 6 TCRs requires 6 separate T-cell gene transfer events



~\$1.5M to generate six TCRs from lentivirus for each patient\*

Bigger Problem: 10 patients with 60 TCRs requires 60 separate gene transfer events, 60 different viruses



## Non-viral solution is scalable:

- To express multiple unique TCRs to target multiple neoantigens
- To produce Multiple TCRs meet demands of tumor target diversity within one patient
- To reduce costs and avoid virus with manufacturing using DNA plasmids

# Ziopharm Collaborating with NCI on End-to-end Solution to Target Solid Tumors





# Sleeping Beauty CD19-specific CAR-T Program

## The Problem: CAR-T Therapy Today

#### Viable business model remains elusive

High cost and reimbursement dynamic is likely unsustainable

Centralized manufacturing adds logistical complexities

Significant time required to deliver to patients Ziopharm

### The Solution: Non-viral Sleeping Beauty ≤ 2-day manufacturing

- Local, very rapid, simplified, scalable manufacturing
- Bioengineering resting T cells with CAR and membrane-bound IL-15 keeps them "young"
- mblL15 may avoid lymphodepletion
- Deliver low numbers of T cells and expand in the body, to avoid cytokine release syndrome
- CD19-specific approved CAR target for autologous T cells

### Strategy for Very-Rapid Manufacturing of CAR-T

√ Demonstrated *Sleeping Beauty* with CD19specific CAR-T

- ✓ Value to Ziopharm
  - CD19: Fully-funded with Eden BioCell
  - o CD19: Fully-funded at MD Anderson
  - o Undisclosed: Additional validated target
- $\sqrt{}$  Not pursuing new CAR targets

## Significant

progress made on cell viability to file with FDA

In the clinic 2H2019

(12)



#### Eden BioCell to take CAR-T CD19 to Asian Markets



- Sleeping Beauty third-generation for very rapid manufacturing of CD19specific CAR-T cell therapy licensed to Eden BioCell for Greater China
- Eden BioCell funded with up to \$35 million entirely from TriArm Therapeutics
- Ziopharm and TriArm each have 50 percent ownership



# Controlled IL-12 Platform

# Recurrent Glioblastoma is not Curable; A New Rational Approach is Needed



## TARGETS ARE

Current therapies don't work



LOW SURVIVAL RATE

 Historical overall survival is 5 to 8 months





## IMMUNOTHERAPY THE PROBLEM BEST APPROACH

Immune system to fight the cancer

Brain tumors exclude or weaken the immune system



#### THE SOLUTION: IL-12 as a DRUG

Most powerful immuno-stimulant to recruit T cells

# IL-12 Delivered into Recurrent Glioblastoma can be Controlled by Ziopharm to Improve Survival



#### IL-12 Monotherapy with Low-dose Steroids Expanded Trial

Phase 1: Ad-RTS-hIL-12 plus 20mg of veledimex

- Expansion cohort of monotherapy and guidance for low dose (<20 mg) dexamethasone</li>
- Enrollment (n=25) completed this week

Ziopharm

65% of enrolled patients received low-dose steroids

#### Next Logical Step: Controlled IL-12 in Combination with PD-1 Inhibitors for recurrent GBM

## Biomarker-driven studies Monotherapy resulted in upregulation of PD-1 in tumor microenvironment

#### **Combination with OPDIVO**

- Phase 1 trial of Controlled IL-12 in combination PD-1 antibody OPDIVO<sup>®</sup> (nivolumab) to treat patients with rGBM
- Enrollment up to 18 patients expected to be complete in 2Q2019

## 

#### New collaboration with Regeneron Pharmaceuticals

- Phase 2 trial of Controlled IL-12 in combination with PD-1 antibody Libtayo<sup>®</sup> (cemiplimab-rwlc) to treat patients with rGBM
- Enroll up to ~30 patients; primary endpoints are safety and efficacy
- Initiate 1H2019

# Summary of 2019 Milestones: Two Platforms Solving Critical Problems

1Q2019	2Q2019	1H2019	Mid-2019	2H2019
Phase 1 Fully enrolled Controlled IL-12 monotherapy expansion cohort	Phase 1 Fully enrolled Controlled IL-12 in combination with OPDIVO	Phase 2 Initiation Controlled IL-12 in combination with Libtayo	Phase 1 First-in-human trial initiation NCI-led <i>Sleeping Beauty</i> TCR-T-cell trial targeting solid tumors	Phase 1 Trial initiation <i>Sleeping Beauty</i> CD19-specific CAR-T third-generation trial with membrane- bound IL-15
Controlled IL-12 Platform			Sleeping Beauty Platform	



#### All Programs in the Clinic in 2019



Ziopharm

