

**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): July 3, 2019

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
Common Stock, par value \$0.001 per share	ZIOP	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 (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 July 3, 2019, Ziopharm Oncology, Inc. (the “Company”) issued a press release announcing Drew Deniger, Ph.D., will join the Company from the National Cancer Institute to lead the Company’s program to genetically modify T cells to express neoantigen-specific T-cell receptors, effective July 29, 2019.

A copy of the press release 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.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated July 3, 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: July 3, 2019



Ziopharm Oncology Names NCI's Dr. Drew Deniger to Direct TCR-T Cell Therapy Program

– Dr. Deniger joins from National Cancer Institute to lead Ziopharm's non-viral T-cell program targeting neoantigens for personalized immunotherapy of solid tumors –

Boston, July 3, 2019 — Ziopharm Oncology, Inc. ("Ziopharm" or "the Company") (Nasdaq:ZIOP), today announced Drew Deniger, Ph.D., will join Ziopharm from the National Cancer Institute (NCI) to lead the company's program to genetically modify T cells to express neoantigen-specific T-cell receptors (TCRs), effective July 29, 2019.

Since 2013, Dr. Deniger has worked at the NCI under Dr. Steven Rosenberg where he has served as Lead Investigator for the group's efforts in three initiatives: Identifying "hotspot" neoantigens for T-cell therapy; targeting neoantigens in metastatic endometrial and ovarian cancers; and non-viral gene therapy using the *Sleeping Beauty* platform to generate TCR-modified T cells targeting neoantigens.

"At the foundation of our TCR-T program is the partnership we have developed with Dr. Rosenberg and his team at the NCI. As an integral part of that group, Dr. Deniger has helped harness our *Sleeping Beauty* technology to express neoantigen-specific T-cell receptors and prepare for the start of the upcoming clinical trial in patients with solid tumors," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm. "As a recognized leader in the identification of neoantigens in hotspots, advancing innovative immunotherapy approaches into the clinic, and with years of expertise with the *Sleeping Beauty* system, we're delighted to welcome Drew to Ziopharm."

Author of multiple peer-reviewed manuscripts describing detection of neoantigen-reactive T cells for personalized cancer immunotherapy and T-cell responses to hotspot mutations, Dr. Deniger has also written validating publications related to the non-viral *Sleeping Beauty* transposon-transposase system. Dr. Deniger is the named inventor on patents related to TCRs recognizing mutated p53 and methods of isolating T cells having antigenic specificity for a p53 cancer specific-mutation, and has been the recipient of numerous awards in cancer immunotherapy.

"Evaluating and validating the *Sleeping Beauty* platform has been one of my research priorities during my time at NCI," said Drew Deniger, Ph.D. "Utilizing *Sleeping Beauty* to genetically modify T cells is an extremely compelling path to treating solid tumors and I am excited to be able to join Laurence and the Ziopharm team as we advance TCR-T into the clinic. We look forward to building out a broad library of TCRs reactive to neoantigens including within KRAS, p53 and EGFR hotspots for use with the *Sleeping Beauty* platform in the future."

Prior to his tenure at the NCI, Dr. Deniger earned B.S. degrees in Chemistry and Biochemistry from the University of Texas at Austin, a M.S. in Cancer Biology and a Ph.D. in Immunology from the University of Texas MD Anderson Cancer Center. His post-doctoral instruction was in the laboratory of Dr. Rosenberg, where he was trained in clinical translation of cancer immunotherapy, including tumor infiltrating lymphocytes (TIL), neoantigen-specific T cells and TCR-T therapy.

Ziopharm and the NCI are partnered through January 2022 in a cooperative research and development agreement (CRADA), under the direction of Dr. Rosenberg, Chief of the Surgery Branch of the NCI, supporting clinical work to evaluate a non-viral approach to manufacturing TCR-T with the *Sleeping Beauty* platform that target solid tumors. With this approach, T cells can be genetically modified to express multiple, neoantigen-specific TCRs, which Ziopharm believes will be foundational technology to successfully targeting and treating metastatic solid tumors.

Last month, Ziopharm announced that the investigational new drug (IND) application submitted by the NCI had received clearance from the U.S. Food and Drug Administration (FDA) for a clinical trial in solid tumors to evaluate TCR-T utilizing Ziopharm's *Sleeping Beauty* platform.

About Ziopharm Oncology, Inc.

Ziopharm Oncology is an immuno-oncology company focused on developing end-to-end cost-effective solutions using its non-viral *Sleeping Beauty* platform for TCR and CAR T-cell therapies and immune-stimulating gene therapy with Controlled interleukin 12 (IL-12). The *Sleeping Beauty* platform genetically modifies T cells with DNA plasmids to express TCRs to target specific antigens in solid tumors and chimeric antigen receptors (CARs) to target CD19 in blood cancers with the Company's 3rd generation T-cell manufacturing process, rapid personalized manufacture (RPM). The *Sleeping Beauty* platform is being advanced in collaboration with the National Cancer Institute, The University of Texas MD Anderson Cancer Center and Eden BioCell. The Company also is developing its Controlled IL-12 platform, or Ad-RTS-hIL-12 plus veledimex, as monotherapy and in combination with immune checkpoint inhibitors to treat brain cancer, including in collaboration with Regeneron Pharmaceuticals.

Note Regarding Forward-Looking Statements

This news 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," and "believes." These statements include, but are not limited to, statements regarding the potential clinical benefits of its TCR-T program in treating patients and the progress and timing of the development of Ziopharm's and the NCI's research and development programs, including the timing for the initiation and completion of its clinical trials. Although Ziopharm's management team 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 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 and maintaining 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 most recent Quarterly Report on Form 10-Q filed by Ziopharm with the Securities and Exchange Commission. We are providing this information as of the date of this press release, and Ziopharm 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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