
**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): October 22, 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 1.01 Entry into a Material Definitive Agreement.

2019 Research and Development Agreement

On October 22, 2019, Ziopharm Oncology, Inc. (the “Company”) and The University of Texas M.D. Anderson Cancer Center (“MD Anderson”) entered into the 2019 Research and Development Agreement (the “2019 Agreement”) pursuant to which the parties agreed to collaborate with respect to the Company’s *Sleeping Beauty* immunotherapy program, which uses non-viral gene transfer to stably express and clinically evaluate neoantigen-specific T-cell receptors (“TCRs”) in T cells. Under the 2019 Agreement, the Company and MD Anderson will, among other things, collaborate on programs to expand the Company’s TCR library and conduct clinical trials. The activities under the 2019 Agreement will be directed by a joint steering committee comprised of two members from the Company and one member from MD Anderson.

Ziopharm will own all intellectual property developed under the 2019 Agreement and will retain all rights to intellectual property for oncology products manufactured using non-viral gene transfer technologies under the Agreement, including the Company’s *Sleeping Beauty* technology. Ziopharm has granted MD Anderson an exclusive license for such intellectual property outside the field of oncology and to develop and commercialize autologous TCR products manufactured using viral gene transfer technologies, and a non-exclusive license for allogeneic TCR products manufactured using viral-based technologies.

The Company has agreed, beginning on January 1, 2021, to reimburse MD Anderson up to a total of \$20 million for development costs under the 2019 Agreement. In addition, the Company will pay MD Anderson royalties on net sales of its TCR products at rates in the low single digits. The Company is required to make performance-based payments upon the successful completion of clinical and regulatory benchmarks relating to its TCR products. The aggregate potential benchmark payments are \$36.5 million, of which only \$3.0 million will be due prior to the first marketing approval of the Company’s TCR products. The royalty rates and benchmark payments owed to MD Anderson may be reduced upon the occurrence of certain events. The Company also agreed that it will sell its TCR products to MD Anderson at preferential prices, and will sell its TCR products in Texas exclusively to MD Anderson for a limited period of time following the first commercial sale of the Company’s TCR products.

The 2019 Agreement will terminate on December 31, 2026 and either party may terminate the 2019 Agreement following written notice of a material breach. The 2019 Agreement also contains customary provisions related to indemnification obligations, confidentiality and other matters.

Warrant Issued in Connection with Execution of 2019 Agreement

In connection with the execution of the 2019 Agreement, on October 22, 2019, the Company issued MD Anderson a warrant to purchase 3,333,333 shares of the Company’s common stock (the “Warrant”). The Warrant has an initial exercise price of \$0.001 per share, expires on December 31, 2026 and vests upon the occurrence of certain clinical milestones.

The Warrant and the shares of Company’s common stock to be issued upon exercise of the Warrant have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. The Company is relying on the private placement exemption from registration provided by Section 4(a)(2) of the Securities Act and in reliance on similar exemptions under applicable state laws.

Amendment to Existing Research and Development Agreement

Also in connection with the execution of the 2019 Agreement, on October 22, 2019, the Company and MD Anderson entered into the Fifth Amendment to Research and Development Agreement (the “Fifth Amendment”), which amended the Research and Development Agreement, dated August 17, 2015 between the parties (the “2015 Agreement”). The 2015 Agreement governed the research and development activities of the parties for the Company’s chimeric antigen receptor (CAR-T) program. The Fifth Amendment extended the term of the 2015 Agreement until December 31, 2026 and amended the terms of the 2015 Agreement to allow cash resources on hand at MD Anderson under the 2015 Agreement to now be used for development costs under the 2019 Agreement. The

rights and obligations of Precigen, Inc. under the 2015 Agreement were previously assigned to the Company pursuant to the Fourth Amendment to Research and Development Agreement which was entered into on September 18, 2019 (the “Fourth Amendment”) with an effective date of October 5, 2018. The Fourth Amendment will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2019.

The foregoing description of the material terms of the 2019 Agreement, the Warrant and the Fifth Amendment does not purport to be complete and is subject to, and is qualified in its entirety by, reference to the 2019 Agreement, the Warrant and the Fifth Amendment, respectively, each of which will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the year ending December 31, 2019 and is incorporated by reference herein. Portions of the 2019 Agreement may be subject to a confidential treatment request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Item 3.02 Unregistered Sales of Equity Securities.

The information contained above in Item 1.01 of this Current Report on Form 8-K is hereby incorporated by reference into this Item 3.02.

Item 7.01 Regulation FD Disclosure.

On October 28, 2019, the Company issued a press release announcing the execution of the 2019 Agreement.

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	<u>Press Release of Ziopharm Oncology, Inc. dated October 28, 2019.</u>

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: October 28, 2019



**Ziopharm Oncology and MD Anderson Cancer Center
Announce New R&D Agreement to Expand TCR-T Program**

- Accelerates capability for TCR library expansion of T-cell receptors (TCRs) targeting neoantigens, including in hotspots –
- Enables two new TCR-T clinical trials at MD Anderson leveraging the Sleeping Beauty non-viral gene transfer platform –
- New lease for larger facility allows for expansion of R&D footprint on MD Anderson campus –

Boston and Houston, October 28, 2019 — Ziopharm Oncology, Inc. (“Ziopharm” or “the Company”) (Nasdaq:ZIOP), and The University of Texas MD Anderson Cancer Center today announced a new research and development agreement relating to Ziopharm’s *Sleeping Beauty* immunotherapy program to use non-viral gene transfer to stably express and clinically evaluate neoantigen-specific T-cell receptors (TCRs) in T cells (referred to as TCR-T).

“We are delighted to deepen our relationship with MD Anderson, which provides treatment to a large and diverse population of cancer patients with solid tumors,” said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of Ziopharm. “This new agreement is a launch point to expand our TCR library and execute two new clinical trials; a trial for utilizing TCRs from the library targeting hotspot mutations in KRAS, TP53 and EGFR, and a second trial for personalized TCRs targeting patient-specific neoantigens.”

“Cell-based immunotherapies have emerged as a powerful new option for treating patients with hematological cancers, but we have not yet had the same success for patients with solid tumors,” said Ferran Prat, Ph.D., J.D., senior vice president for Research Administration and Industry Ventures at MD Anderson. “We are pleased to be working with Ziopharm to advance a new generation of cell therapies, and we are hopeful they can one day be effective in treating a broader group of our patients.”

Under the terms of the new agreement, Ziopharm commits to fund an additional \$20 million for this expanded work in the TCR-T program through 2023, as well as certain milestone payments for clinical development or regulatory approval in the U.S., European Union, Japan and the rest of the world. The funding for this new agreement was included within the budget forecast provided by Ziopharm in its second quarter 2019 financial results news release and webcast commentary.

MD Anderson will receive low, single-digit royalties on net sales in the U.S. and international markets, as well as warrants for Ziopharm common stock which vest upon achievement of clinical milestones. According to institutional guidelines, MD Anderson has implemented an Institutional Conflict of Interest Management and Monitoring Plan to manage this research.

This new agreement expands the relationship between Ziopharm and MD Anderson, established under a 2015 research agreement related to CD19-specific CAR-T. Earlier this month, the Food and Drug Administration cleared an IND application for a phase 1 clinical trial to evaluate CD19-specific CAR-T, manufactured and infused within two days of gene transfer using Ziopharm's rapid personalized manufacture (RPM), as an investigational treatment for patients with relapsed CD19+ leukemias and lymphomas. Ziopharm has approximately \$20 million of pre-funded R&D at MD Anderson under the prior agreement, which may now be used under the new agreement, for both the CAR-T or TCR-T initiatives.

In addition to the new research and development agreement, Ziopharm has entered a lease agreement with MD Anderson through which the company accesses additional laboratory and office space within the institution's campus. This new facility will serve as home for Ziopharm's expanded Houston office, under the direction of Eleanor de Groot, Ph.D., EVP, GM Cell Therapy and Drew Deniger, Ph.D., head of Ziopharm's TCR-T cell therapy program.

About MD Anderson

The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's most respected centers focused on cancer patient care, research, education and prevention. The institution's sole mission is to end cancer for patients and their families around the world. MD Anderson is one of only 50 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No.1 for cancer care in U.S. News & World Report's "Best Hospitals" survey. It has ranked as one of the nation's top two hospitals for cancer care since the survey began in 1990, and has ranked first 15 times in the last 18 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

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 neoantigens inside and outside hotspots for solid tumors and chimeric antigen receptor (CAR) to target CD19 for blood cancers using the Company's RPM to produce and release CAR-T within two days of gene transfer. 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.

Forward-Looking Statements Disclaimer

This press 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 activities and benefits of the collaboration between Ziopharm and MD Anderson, including the Company's expectations regarding future clinical trials, and the progress and timing of the Company's research and development programs. 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 the plans or priorities of MD Anderson and Ziopharm, 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 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 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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