

**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): May 6, 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
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 2.02 Results of Operations and Financial Condition

On May 6, 2021, Ziopharm Oncology, Inc., or the Company, issued a press release announcing its financial condition and results of operations for the three months ended March 31, 2021. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information provided in this Item 2.02 of Form 8-K, including Exhibit 99.1 hereto, 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 liabilities of that section, nor shall it be deemed incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 2.05 Costs Associated with Exit or Disposal Activities

On May 6, 2021, the Company announced its commitment to a plan to realign its research and development resources to wind down the clinical trials of its Controlled IL-12 program as part of the Company’s decision to allocate an increasing amount of its resources and capital to its Sleeping Beauty TCR program. Pursuant to this plan, the Company will eliminate approximately 15% of its existing workforce on a staggered basis over the remainder of 2021. Affected employees will be offered separation benefits, including severance payments and, in some cases, retention bonuses, along with temporary healthcare coverage assistance. Additionally, the Company is evaluating its facilities and vendor relationships utilized in the Controlled IL-12 program and the associated contractual obligations to determine the appropriate course of action and any associated charges to wind down the ongoing clinical trials. The Company estimates the severance and termination-related costs to be approximately \$830 thousand and will record these charges in the second quarter of 2021.

Forward-Looking Statements

The disclosure contained in this Current Report on Form 8-K contains certain forward-looking information about the Company 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. Words such as “expect(s),” “feel(s),” “believe(s),” “will,” “may,” “anticipate(s)” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding the benefits of the proposed restructuring program, the anticipated timing and details of the reduction in force, expected charges and costs associated with the reduction in workforce that the Company expects to incur in the second quarter of 2021. These statements are based on current expectations, estimates and projections about the Company’s business based, in part, on assumptions made by management, and are subject to a number of risks and uncertainties. Factors that could cause actual results to differ materially from current expectations include possible changes in the expected costs and charges associated with the reduction in force, and risks associated with the Company’s ability to achieve the expected benefits of the reduction in force and realignment of its resources. Additionally, these forward-looking statements should be considered in conjunction with the cautionary statements and risk factors described in the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, as amended, and its other filings with the SEC.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Ziopharm Oncology, Inc. dated May 6, 2021
10.4	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.

By: /s/ Timothy Cunningham
Name: Timothy Cunningham
Title: Chief Financial Officer

Date: May 6, 2021



Ziopharm Oncology Reports First Quarter 2021 Financial Results and Provides Corporate Updates

– Annual shareholder meeting planned for May 19, 2021

– Company to host conference call today at 4:30 pm ET

Boston, May 6, 2021 — Ziopharm Oncology, Inc. (“Ziopharm” or the “Company”) (Nasdaq: ZIOP), today announced its financial results for the first quarter ended March 31, 2021 and provided additional corporate updates. The Company will host a conference call and webcast today at 4:30 pm ET.

Recent Corporate Highlights and Updates

- Announced that the infusion of the first patient in the CD19-Specific Rapid Personalized Manufacturing (RPM) CAR-T Phase I Clinical Trial being conducted in Taiwan by the Company’s Joint Venture partner, Eden BioCell, occurred in March.
- Presented a poster entitled “*Hotspot mutations in KRAS and TP53 targeted by TCR-T cells genetically modified with the Sleeping Beauty transposon/transposase system*” at the American Association for Cancer Research (AACR) Virtual 2021 Annual Meeting.
- Completed construction of the GMP facility in Houston with follow on activities for facility qualification and validation to take place over the summer. The Company will then qualify the manufacturing process in the facility and file an IND amendment to enable GMP manufacturing to supplement its CMO partner’s capacity for the TCR-T hotspot trial.
- Announced it is winding down its existing Controlled IL-12 clinical program. Data indicated potential clinical benefits in a variety of cancers, including recurrent glioblastoma. The Company will continue to seek a partner for this program while re-deploying resources and will explore synergies between this technology and its cell therapy programs. The Company anticipates a headcount reduction of approximately 15% related to this wind down.
- Anticipate the closure of the CD19 RPM CAR-T Allogeneic Phase I Trial at MD Anderson Cancer Center. The trial closure is expected to occur during the second or third quarter of 2021.
- Plans to hold its Annual Meeting of Stockholders on May 19, 2021 at 9:00 am EDT. The meeting will be held virtually. Shareholders and interested stakeholders may attend the annual meeting online using the link below. Shareholders may submit questions during the meeting and vote shares electronically during the meeting by visiting www.virtualshareholdermeeting.com/ZIOP2021.

“Our first quarter was highlighted by execution and important strategic decisions that focus our capital on our prioritized development programs,” said Heidi Hagen, Chief Executive Officer of Ziopharm. “In the coming months, we are focused on delivering important milestones on our clinical trials, including our first TCR-T trial, where we plan to treat patients beginning in the second half of the year, and continued progress on the Eden BioCell CD19-specific RPM CAR-T Trial in Taiwan.”

First Quarter 2021 Financial Results

- Research and development expenses were \$13.3 million for the first quarter of 2021, compared to \$12.7 million for the first quarter of 2020, primarily reflecting increased manufacturing activity and headcount.
- General and administrative expenses were \$8.2 million for the first quarter of 2021, compared to \$6.0 million for the first quarter of 2020. The increase in general and administrative expenses is primarily due to increased employee related expenses and legal costs associated with its expanded patent portfolio and facility costs.
- Net loss for the first quarter of 2021, was \$21.6 million, or \$(0.10) per share, compared to a net loss of \$18.3 million, or \$(0.09) per share, for the first quarter of 2020.
- Cash and cash equivalents, as of March 31, 2021 were \$100.1 million.
- Additionally, a prepayment of approximately \$5.1 million remains for work to be conducted by the Company at MD Anderson under the Company’s research and development agreements.

Earnings Conference Call and Webcast

Ziopharm will host a conference call and webcast for the investment community today, May 6, 2021, at 4:30 p.m. EDT. The conference call can be accessed by dialing 855-327-6837 (U.S. and Canada) or 631-891-4304 (International). The passcode for the conference call is 10013973. The live webcast may be accessed using the link here, or by visiting the “Investors” section of the Ziopharm website at www.ziopharm.com. The call will be recorded and available for replay on the Company’s website for approximately 90 days after the call.

Annual Meeting of Stockholders

Ziopharm will host its annual meeting virtually on May 19, 2021 at 9:00 am. Shareholders and interested stakeholders may attend the meeting, submit questions, and vote their shares electronically during the meeting by visiting www.virtualshareholdermeeting.com/ZIOP2021.

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 rapidly manufactured Sleeping Beauty-enabled CD19-specific CAR-T program and a precisely controlled IL-12 gene therapy. 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.

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 Company's business and strategic plans, the wind down of the Company's Controlled IL-12 clinical program, the anticipated closure of the CD19 RPM CAR-T Allogeneic Phase I Trial at MD Anderson Cancer Center, the timing of activities relating to the Company's GMP facility, and the timing of the Company's research and development programs, including the anticipated dates for enrolling patients in the Company's TCR-T clinical trial. 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 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 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 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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ZIOPHARM Oncology, Inc**Statement of Operations
(unaudited)****(in thousands except per share data)**

	For the Three Months ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 13,336	\$ 12,706
General and administrative	8,227	5,954
Total operating expenses	21,563	18,660
Loss from operations	(21,563)	(18,660)
Other income, net	9	367
Net loss	\$ (21,554)	\$ (18,293)
Net income (loss) applicable to common stockholders	\$ (21,554)	\$ (18,293)
Basic and diluted net loss per share	\$ (0.10)	\$ (0.09)
Weighted average number of common shares outstanding used to compute basic and diluted net loss per share	213,954,665	199,814,768

ZIOPHARM Oncology, Inc**Selected Balance Sheet Data
(unaudited)**

	March 31, 2021	December 31, 2020
Cash and cash equivalents	\$100,056	\$ 115,069
Working capital	\$ 93,749	\$ 112,221
Total assets	\$128,472	\$ 146,345
Total stockholders' equity	\$105,641	\$ 123,982