

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): February 25, 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 February 25, 2021, Ziopharm Oncology, Inc., or the Company, issued a press release announcing its financial condition and results of operations for the three months and year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information provided in this 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 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Ziopharm Oncology, Inc. dated February 25, 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: February 25, 2021



Ziopharm Oncology Provides Leadership and Corporate Updates; Reports Fourth Quarter and Full Year 2020 Financial Results

Heidi Hagen Appointed Interim Chief Executive Officer Replacing Dr. Laurence Cooper; Search for Permanent CEO Initiated

Dr. Laurence Cooper Expected to Continue with Company in a Scientific Advisory Role

James Huang Appointed Executive Chairman and Board Refreshment Completed

FDA IND Clearance Announced for Groundbreaking Library TCR-T Phase I/II Clinical Trial, Targeting Six "Hotspot" Mutations in KRAS and TP53

Further Details Provided on R&D Day on March 11 Including Participation of Dr. Steven Rosenberg, Dr. Carl June, and Dr. Scott Kopetz

Boston, February 25, 2021 (GLOBE NEWSWIRE) — Ziopharm Oncology, Inc. ("Ziopharm" or the "Company") (Nasdaq: ZIOP), today announced its financial results for the fourth quarter and year ended December 31, 2020 and provided several additional corporate updates. The Company will host a conference call and webcast today at 4:30 pm ET.

Leadership Transition and Planning

The Company today announced that Heidi Hagen, formerly Lead Independent Director, has been appointed Interim Chief Executive Officer, replacing Dr. Laurence Cooper, MD., Ph.D. effective February 25, 2021. Ms. Hagen is remaining a member of the Board of Directors.

Dr. Cooper is also stepping down from his seat on the Board of Directors and is expected to continue with the Company in a scientific advisory capacity to support the Company's R&D programs. A search for a permanent Chief Executive Officer is underway.

Dr. Cooper said, "With the fantastic news we announced today regarding the IND clearance of our Library TCR-T clinical studies, the Company is well positioned as a leader in immuno-oncology using engineered T-cells. I will work with the Board on transitioning to an advisory

role to support the organization on the science side, while allowing the Company to identify a complementary business leader who can drive our path to commercialization.”

Ms. Hagen added, “One cannot overstate Laurence’s contribution to Ziopharm. His life’s work has been to bring innovation and hope to patients suffering from the devastating impact of cancer. We will continue down the path Laurence has laid before us, and look forward to his continued involvement to help us address the scientific challenges ahead.”

Ms. Hagen has served on the Board since June 2019. She 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 Company also announced today that James Huang has been appointed Executive Chairman of the Board effective February 25, 2021.

Mr. Huang said, “On behalf of the entire Board we thank Laurence for his leadership and vision and express our full support for Heidi while we conduct a comprehensive search for a permanent CEO. We will strive to identify a leader with the business acumen to drive critical portfolio, development, commercial planning and capital allocation decision making that will help ensure the success of the Company.”

Mr. Huang has served on the Board since July 2020 and has served as Chairman since January 2021. He 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.

FDA IND Clearance for the Company’s Library TCR-T Clinical Phase I/II Trial

The Company today announced it has received IND clearance by the U.S. Food and Drug Administration (FDA) for the Company’s TCR-T trial utilizing six “hotspot” TCRs from its library. The Company anticipates enrolling patients in the Phase I/II clinical trial across a variety of solid tumor cancers in the second half of the year.

The Company is working closely with MD Anderson to begin identifying patients for this trial. The trial will address a range of solid tumors, across gynecologic, colorectal, pancreatic, non-small cell lung and cholangiocarcinoma cancers.

“We are very excited to have received clearance for this IND and look forward to initiating the Library TCR-T trial, representing a tremendous amount of work by the team and the culmination of efforts by so many dedicated employees,” said Dr. Eleanor de Groot, Ph.D., Executive Vice

President and General Manager of Cell Therapy of Ziopharm. “We believe our cell therapy *Sleeping Beauty* platform technology has the potential to deliver non-viral engineered T-cell therapies to address significant unmet patient need and are excited by this important transition to clinical development for the Library program.”

Additional Details Regarding R&D Day March 11, 2021

The Company provided additional details regarding the previously announced virtual R&D Day focusing on cell therapy on Thursday, March 11, 2021 at 11:00 am ET. Members of Ziopharm’s management team will provide an overview of the Company’s strategy, programs, and pipeline.

The session will also include presentations by leading key opinion leaders: Dr. Steven Rosenberg, Chief of Surgery at the National Cancer Institute; Dr. Carl June, Chair of the Ziopharm Scientific Advisory Board and Director of the Center for Cellular Immunotherapies and Director of Translational Research in the Abramson Cancer Center of the University of Pennsylvania; and Dr. Scott Kopetz, Colorectal Cancer Physician Scientist, NCI Colon Task Force Chair, Professor, and Deputy Chair at The University of Texas, MD Anderson Cancer Center.

“We are very excited to share updates on our suite of distinctive cell therapy programs and delighted to have top key opinion leaders joining us to provide their views and perspectives. We will be highlighting the unique attributes of Ziopharm and the encouraging progress in our programs,” said Dr. Raffaele Baffa, M.D., Ph.D., Chief Medical Officer of Ziopharm.

Fourth Quarter 2020 Financial Results

- Research and development expenses were \$14.0 million for the fourth quarter of 2020, compared to \$10.2 million for the fourth quarter of 2019, primarily reflecting increased clinical trial activity.
- General and administrative expenses were \$8.8 million for the fourth quarter of 2020, compared to \$5.8 million for the fourth quarter of 2019. The increase in general and administrative expenses for the fourth quarter of 2020 is primarily due to increased legal costs, investor relations costs and facility charges.
- Net loss for the fourth quarter of 2020, was \$22.8 million, or \$(0.11) per share, compared to a net loss of \$15.7 million, or \$(0.09) per share, for the fourth quarter of 2019.

- Cash and cash equivalents, as of December 31, 2020 were \$115.1 million. This cash position is sufficient to fund Company operations into the second quarter of 2022.
- A prepayment of approximately \$8.1 million remains for work to be conducted by the Company at MD Anderson under the Company's research and development agreements.

Full Year 2020 Financial Results

- Net loss applicable to the common shareholders for the year ended December 31, 2020 was \$80.0 million, or \$(0.38) per share, basic and diluted, compared to net loss applicable to the common shareholders of \$117.8 million, or \$(0.70) per share, basic and diluted, for the year ended December 31, 2019.
- Research and development expenses were \$52.7 million for the year ended December 31, 2020, compared to \$38.3 million for the year ended December 31, 2019. The increase in research and development expenses for the year ended December 31, 2020 is primarily due to increased manufacturing, headcount, and clinical trial activity.
- General and administrative expenses were \$27.7 million for the year ended December 31, 2020, compared to \$19.5 million for the year ended December 31, 2019. The increase in general and administrative expenses for the year ended December 31, 2020 is primarily due to increased legal costs, investor relations costs and facility charges.

Fourth Quarter and Full Year 2020 Results Conference Call and Webcast Details

Ziopharm will host a conference call and webcast for the investment community today, February 25, 2021, at 4:30 pm ET. The conference call can be accessed by dialing 877-451-6152 (U.S. and Canada) or +1-201-389-0879 (International). The passcode for the conference call is 13715482. To access the live webcast or the subsequent archived recording, click [here](#) or visit the "Investors" section of the Ziopharm website at www.ziopharm.com. The webcast will be recorded and available for replay on the company's website for 90 days.

R&D Day Conference Call and Webcast Details – March 11, 2021, 11:00am ET

Interested participants can register for and view the webcast using [this link](#) or by visiting the "Investors" section of the Ziopharm website at www.ziopharm.com. The live Q&A session can be accessed by dialing 866-548-4713 (U.S. and Canada) or +1-323-794-2093 (International). The conference ID for the call is 5859801. The session will be recorded and available for replay on the Company's website for 90 days.

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.

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 availability of its capital resources, the Company’s organization and leadership, and the progress, design and timing of the Company’s research and development programs, including the anticipated dates for enrolling patients in 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 Eden BioCell’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 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.
Statements of Operations
(in thousands except share and per share data)
(unaudited)

	Three Months Ended December 31, (unaudited)		Year Ended December 31, (unaudited) (audited)	
	2020	2019	2020	2019
	Operating expenses:			
Research and development	\$ 13,971	\$ 10,216	\$ 52,696	\$ 38,331
General and administrative	8,803	5,820	27,665	19,527
Total operating expenses	22,774	16,036	80,361	57,858
Loss from operations	(22,774)	(16,036)	(80,361)	(57,858)
Other income (expense), net	2	290	385	813
Noncash inducement warrant expense	—	—	—	(60,751)
Net loss	(22,772)	(15,746)	(79,976)	(117,796)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.09)	\$ (0.38)	\$ (0.70)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	213,028,832	179,522,225	209,636,456	167,952,114

ZIOPHARM Oncology, Inc.
Balance Sheet Data
(in thousands)

	December 31,	
	(unaudited) 2020	(audited) 2019
Cash and cash equivalents	\$ 115,069	\$ 79,741
Working capital	\$ 112,221	\$ 92,966
Total assets	\$ 146,345	\$ 109,114
Total stockholders' equity	\$ 123,982	\$ 95,010