

**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): August 6, 2020

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 | 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 August 6, 2020, Ziopharm Oncology, Inc., or the Company, issued a press release announcing its financial condition and results of operations for the three months ended June 30, 2020. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

This information, including the information contained in the press release furnished as Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any of the Company’s filings, whether made before or after the date hereof, regardless of any general incorporation language in any 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 August 6, 2020 |
| 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/ Satyavrat Shukla

Name: Satyavrat Shukla

Title: Executive Vice President and Chief Financial Officer

Date: August 6, 2020



Ziopharm Oncology Reports Second Quarter 2020 Financial Results and Provides Corporate Update

- Enrollment completed in Controlled IL-12 phase 2 clinical trial with Regeneron's Libtayo® –
- First patient with DIPG dosed in phase 1/2 pediatric brain tumor trial of Contolled IL-12 –
- Work restrictions at the NCI and MD Anderson easing; MD Anderson initiated phase 1 CD19-specific CAR-T clinical trial using RPM –
- Eden BioCell on track for Taiwan IND filing for autologus CAR-T clinical trial this year –

Company to host conference call and webcast today, August 6, at 4:30 p.m. EDT

Boston, August 6, 2020 — Ziopharm Oncology, Inc. ("Ziopharm" or the "Company") (Nasdaq: ZIOP), today announced its financial results for the second quarter ended June 30, 2020 and provided a corporate update.

"During the second quarter, we were able to report positive clinical and organizational progress, positioning the Company for additional data readouts in the coming year," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer. "With the completion of enrollment in our phase 2 trial of Controlled IL-12 in combination with Libtayo, and launches of two new trials, we have begun to see encouraging signs of our partners re-emerging despite the COVID-19 outbreak."

Recent Corporate Highlights

Sleeping Beauty TCR-T Program

- **NCI Phase 2 Personalized TCR-T Trial.** During the quarter and in recent weeks, the Ziopharm team collaborated with the National Cancer Institute (NCI) to advance manufacturing preparations for dosing the first patient in this first-in-human non-viral TCR-T study ([NCT0402436](#)). As NCI laboratory functions gradually re-open, the team there is once again proactively screening patients for neoantigens and T-cell receptors (TCRs) to render them eligible for the trial. Ziopharm has been able to use its newly expanded laboratories in Houston to complete required engineering runs and provided that information to the NCI to help expedite their enrollment to the trial.
- **Personalized and Library TCR-T Clinical Trials with MD Anderson.** Based on interactions with the U.S. Food and Drug Administration (FDA), the Company continues to make progress toward finalizing the design of its TCR-T clinical trials at MD Anderson based on the *Sleeping Beauty* platform and clearance of an Investigational New Drug (IND) application to the FDA in Q1 2021. The Company plans to evaluate both its personalized TCR-T and its library TCR-T therapies and is focused on completing IND-enabling CMC (chemistry, manufacturing and controls) and nonclinical data package to support those opportunities. Given its progress assembling a TCR library, the Company expects the trial using these allogeneic receptors to begin enrollment first, with anticipated cancer indications of gynecologic, colorectal, pancreatic, non-small cell lung cancer and cholangiocarcinoma.

Controlled IL-12 Program

- **Phase 2 Combination Study.** Ziopharm announced completion of enrollment in June of its phase 2 combination trial of Controlled IL-12 with Regeneron's Libtayo® to treat patients with recurrent glioblastoma (rGBM). Per the [study protocol](#), 40 patients were enrolled at 7 sites, of whom 39 were dosed with the combination. Initial data is expected to be submitted for presentation later this year.
- **Pediatric Trial.** The Company recently announced that the first patient with diffuse intrinsic pontine glioma (DIPG) had been dosed in its phase 1/2 study of Controlled IL-12 for the treatment of pediatric brain tumors. The trial ([NCT03330197](#)) is designed to evaluate the safety and tolerability of a single intratumoral injection of Ad-RTS-hIL-12 with up to 14 days of oral vedimex in children with gliomas. Up to 12 patients with DIPG may be enrolled in phase 1 of the study, which is being conducted at leading pediatric cancer centers across the United States, including Lurie Children's Hospital in Chicago, the Dana-Farber Cancer Institute in Boston and the University of California in San Francisco.
- **ASCO 2020.** The Company provided positive clinical updates at the 2020 American Society of Clinical Oncology (ASCO) virtual annual meeting in late May. Continued follow-up from Controlled IL-12 monotherapy studies reinforced encouraging median overall survival, while Controlled IL-12 in combination with a PD-1 inhibitor demonstrated a favorable safety profile and encouraging initial survival data. Additional data are expected to be presented later this year.

Sleeping Beauty CAR-T Program

- **Eden BioCell CAR-T Study.** The Company's joint venture partner, Eden BioCell, continued to make progress toward filing an IND this year for a clinical trial in Taiwan to assess patient-derived (autologous) CD19-specific membrane bound IL-15 CAR-T cells, produced using Rapid Personalized Manufacturing (RPM) technology designed to reduce cost and simplify production for infusion the day after gene transfer.
- **Ziopharm CAR-T Study.** The Company's clinical collaborators at MD Anderson Cancer Center were able to complete necessary preparations and commence enrollment in the phase 1 clinical trial infusing donor-derived (allogeneic) CD19-specific CAR-T therapies produced using RPM. Up to 24 patients with advanced CD19+ leukemias and lymphomas who have relapsed after allogeneic bone marrow transplantation will be enrolled in this investigator-initiated trial ([NCT03579888](#)).

Operational

- **Expanded Board of Directors.** Ziopharm recently announced the appointment of James Huang to the Company's Board of Directors. Mr. Huang is a Managing Partner at Kleiner Perkins Caufield & Byers China and 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.
- **Scientific Advisory Board.** In June, the Company announced the appointment of renowned oncology and immunotherapy pioneer, Carl June, M.D., as Chairman of its newly formed Scientific Advisory Board (SAB). Dr. June is recognized in the oncology field for his groundbreaking work in the development and commercialization of gene therapy and T-cell therapies. The SAB will provide strategic counsel to guide the efficient development of Ziopharm's innovative technologies and pipeline of immunotherapies.

Second Quarter 2020 Financial Results

- Research and development expenses were \$12.1 million for the second quarter of 2020, compared to \$10.0 million for the second quarter of 2019, primarily reflecting increased clinical trial activity.
- General and administrative expenses were \$6.6 million for the second quarter of 2020, compared to \$4.8 million for the second quarter of 2019. The increase in general and administrative expenses for the second quarter of 2020 is primarily due to increased headcount, legal costs associated with its expanded patent portfolio and facility costs.
- Net loss for the second quarter of 2020, was \$18.6 million, or \$(0.09) per share, compared to a net loss of \$14.6 million, or \$(0.09) per share, for the second quarter of 2019.
- Cash and cash equivalents, as of June 30, 2020 were \$153.5 million.
- A prepayment of approximately \$14.0 million remains for work to be conducted by the Company at MD Anderson under the Company's research and development agreements.

Conference Call and Webcast

Ziopharm will host a conference call and webcast for the investment community today, August 6, 2020, at 4:30 p.m. EDT. The conference call can be accessed by dialing 1-877-451-6152 (U.S. and Canada) or 1-201-389-0879 (international). The passcode for the conference call is 13706729. 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 two weeks.

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 a solid tumor each year. With its multiplatform approach, Ziopharm is at the forefront of immuno-oncology with a goal to treat any type of solid tumor. 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 partnerships with the National Cancer Institute, The University of Texas MD Anderson Cancer Center and others. 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 and the progress, design and timing of the Company's research and development programs, including the anticipated dates for the clearance of the IND for its TCR-T clinical trial and the submission of the IND by Eden BioCell, enrollment expectations for its CAR-T and DIPG clinical trials, and the timing for the data readouts for its Controlled IL-12 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 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. In addition, the extent to which the COVID-19 pandemic impacts the Company's business, clinical development and regulatory efforts and the value of its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects. 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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– Financial Tables Follow –

ZIOPHARM Oncology, Inc.
Statements of Operations
(in thousands except share and per share data)
(unaudited)

| | Three Months Ended June 30, (unaudited) | |
|---|---|-------------|
| | 2020 | 2019 |
| Operating expenses: | | |
| Research and development | \$ 12,051 | \$ 9,988 |
| General and administrative | 6,555 | 4,755 |
| Total operating expenses | 18,606 | 14,743 |
| Loss from operations | (18,606) | (14,743) |
| Other income, net | 10 | 133 |
| Net loss | (18,596) | (14,610) |
| Basic and diluted net loss per share | \$ (0.09) | \$ (0.09) |
| Weighted average common shares outstanding used to compute basic and diluted net loss per share | 212,792,403 | 160,789,272 |

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

| | June 30, 2020 | December 31, 2019 |
|----------------------------|------------------|----------------------|
| Cash and cash equivalents | 153,521 | 79,741 |
| Working capital | 156,064 | 92,966 |
| Total assets | 181,679 | 109,114 |
| Total stockholders' equity | 163,414 | 95,010 |

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