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 7, 2020

ZIOPHARM Oncology, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-33038	84-1475642
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One First Avenue, Parris Building 34, Navy Yard Plaza Boston, Massachusetts	02129
(Address of Principal Executive Offices)	(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 May 7, 2020, 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, 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

Exhibit No.	Description
99.1	Press Release of Ziopharm Oncology, Inc. dated May 7, 2020
104	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

Date: May 7, 2020

Name: Satyavrat Shukla

Title: Executive Vice President and Chief Financial Officer

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

– Regulatory discussions with FDA advance Ziopharm TCR-T IND process –

– Enrollment on track in Controlled IL-12 phase 2 clinical trial with Regeneron's Libtayo ®;

Controlled IL-12 clinical data update at ASCO 2020 –

– Work restrictions at NCI and MD Anderson impacting clinical trials;

Ziopharm working to minimize delays –

– Prioritizing Greater China CAR-T clinical trial given advancements –

– Balance sheet strengthened in Q1; cash of $171 million to fund operations into mid-2022 –

Company to host conference call and webcast today, May 7, at 4:30 p.m. EDT

Boston, May 7, 2020 — Ziopharm Oncology, Inc. ("Ziopharm" or the "Company") (Nasdaq: ZIOP), today announced its financial results for the first quarter ended March 31, 2020 and provided a corporate update.

"We anticipate reporting milestones across all of our programs this year, even when factoring in the effects of the pandemic on our global community, and we are working to minimize the uncertainty around some of of our timelines," said Laurence Cooper, M.D., Ph.D., Chief Executive Officer. "We continue to make progress toward initiating our TCR-T clinical trial at MD Anderson Cancer Center based on the *Sleeping Beauty* platform and look forward to providing an update on the status of this trial later this year. In our Controlled IL-12 platform for recurrent glioblastoma (rGBM), clinicians and healthcare workers continue to treat patients and facilitate patient enrollment and our anticipated milestones in this program are on track. The National Cancer Institute (NCI) and MD Anderson have limited nonclinical and clinical research in response to COVID-19 which impacts their partners, and which will temporarily delay the initiation of our clinical trials with each institution. We are working closely with them to undertake our trials once the restrictions ease; however, the timing is not under our control."

"The Company is in a strong financial position, having completed a financing during the first quarter prior to the impact of the pandemic in the United States," added Sath Shukla, Chief Financial Officer. "With over $170 million in cash and investments available to support our programs, we are well positioned to weather this storm and continue executing on our strategic objectives."

Recent Corporate Highlights

Sleeping Beauty TCR-T Program

- **NCI Phase 2 TCR-T Study**. During the quarter, the Ziopharm team worked with the NCI to advance preparations for dosing the first patient, including work on screening patients and final engineering

runs. As a result of COVID-19, the NCI has instituted significant work restrictions which unavoidably impacts research with its partners and have in turn delayed the dosing of the first patient in our TCR-T trial under the CRADA. Ziopharm is able to use its expanded laboratories in Houston to help complete the engineering runs and reduce future delays for this trial. The study is the first-in-human non-viral TCR-T study to be conducted at the NCI and details on the protocol are available on clinicaltrials.gov (NCT0402436).

- **Personalized and Library TCR-T Clinical Trial with MD Anderson.** Based on instructive feedback from the U.S. Food and Drug Administration (FDA), the Company continues to make progress toward initiating its TCR-T clinical trial at MD Anderson based on the *Sleeping Beauty* platform. As previously guided, the Company plans to evaluate both its personalized TCR-T and its library TCR-T therapies and, in preparation for this trial, the Company has increased its R&D footprint at MD Anderson by leasing additional research and development facilities.

Controlled IL-12 Program

- **Phase 2 Combination Study**. Under the Controlled IL-12 program, Ziopharm is actively enrolling patients in a phase 2 combination trial with Regeneron's Libtayo® to treat patients with rGBM. Per the study protocol, the Company expects to enroll at least 36 patients at approximately 10 sites. Enrollment for this study is anticipated to be completed in H1 2020. Accrual to the phase 1 monotherapy expansion protocol (NCT03679754) and combination study with OPDIVO® were completed in 2019 (NCT03636477). The Company anticipates providing clinical updates at the 2020 American Society of Clinical Oncology virtual annual meeting in late May.

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 CAR-T therapies, produced using a technology we refer to as Rapid Personalized Manufacturing (RPM).
- **Ziopharm CAR-T Study.** The Company's planned clinical trial infusing donor-derived (allogeneic) CD19-specific CAR-T therapies produced using RPM has been impacted by MD Anderson's response to COVID-19, which impacts all their partners. This will unavoidably delay the dosing of the first patient in this trial. Institutional and federal regulatory documents are complete, manufacturing has been verified, but the site initiation visit is delayed due to the current work restrictions at MD Anderson. In response to COVID-19 and other considerations, the Company is prioritizing the work with Eden BioCell to develop autologous CAR-T under RPM given Eden BioCell's technical progress and the favorable work environment in Taiwan, despite the pandemic. This helps conserve the Company's financial resources while preserving Ziopharm's rights to advance the technology in the U.S. and leverage clinical data from Greater China. Data from Eden BioCell and Ziopharm will collectively support the development of RPM technology.

Operational

- **Expanded Team, Board, and Capabilities.** Ziopharm selectively expanded its team with new employees in cell therapy, manufacturing and clinical operations to further advance its programs, expand its capabilities and support its growth especially in Houston. The Company is recruiting additional personnel, including a Chief Medical Officer, and strengthening its business development and investor relations capabilities. Ziopharm also plans to selectively add to its Board of Directors, complementing its existing leadership in drug development, financing, and business development.

- **Strengthened Balance Sheet**. The Company successfully raised over $100 million in net proceeds during the first quarter, extending its funding horizon into mid-2022. The additional funding provides for an accelerated buildout of its TCR-T program in Houston and the launch of Ziopharm-led TCR clinical trials for patients with solid tumors. The Company ended the first quarter of 2020 with approximately $171 million in cash, and another $18 million in capital pre-funded by MD Anderson available for the Company's programs.

First Quarter 2020 Financial Results

- Research and development expenses were $12.7 million for the first quarter of 2020, compared to $9.5 million for the first quarter of 2019, primarily reflecting increased clinical trial activity.
- General and administrative expenses were $6.0 million for the first quarter of 2020, compared to $4.1 million for the first quarter of 2019. The increase in general and administrative expenses for the first quarter of 2020 is primarily due to increased headcount, legal costs associated with its expanded patent portfolio and facility costs.
- Net loss for the first quarter of 2020, was $18.3 million, or $(0.09) per share, compared to a net loss of $13.4 million, or $(0.08) per share, for the first quarter of 2019.
- Cash and cash equivalents, as of March 31, 2020 were $171.0 million.
- A prepayment of approximately $18.0 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, May 7, 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 13701877. 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, the availability of cash resources, the Company's hiring expectations and expected additions to its Board of Directors, the progress, design and timing of the

Company's research and development programs, including the anticipated dates for the initiation, completion and readouts of its clinical trials, the Company's expectations regarding the number of patients in its clinical trials, and the Company's expectations regarding the impact of the ongoing COVID-19 pandemic, including the expected duration of disruption and immediate and long-term impact and effect on its business and operations. 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 March 31, (unaudited)	
	2020	2019
Operating expenses:		
Research and development	$ 12,706	$ 9,476
General and administrative	5,954	4,145
Total operating expenses	18,660	13,621
Loss from operations	(18,660)	(13,621)
Other income, net	367	187
Net loss	(18,293)	(13,434)
Basic and diluted net loss per share	$ (0.09)	$ (0.08)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	199,814,768	160,640,859

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

	March 31, 2020	December 31, 2019
Cash and cash equivalents	171,002	79,741
Working capital	175,041	92,966
Total assets	198,279	109,114
Total stockholders' equity	180,337	95,010

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