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 8, 2019

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)).

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. ☐

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**	**NASDAQ Capital Market**

Item 2.02 Results of Operations and Financial Condition

On May 8, 2019, 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, 2019. 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 8, 2019

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/ Kevin G. Lafond
Name: Kevin G. Lafond
Title: Senior Vice President Finance, Chief Accounting Officer and Treasurer

Date: May 8, 2019

Ziopharm Oncology Reports First Quarter 2019 Financial Results and Reaffirms Clinical Timelines

- Phase 1 Trial of Sleeping Beauty *TCR-T cell therapy for patients with solid tumors to begin at NCI in mid-2019 –*
- Third-generation Sleeping Beauty *CD19-specific CAR-T U.S. trial to begin in 2H2019 –*
- Phase 2 trial of Controlled IL-12 in combination with Regeneron's Libtayo® for patients with rGBM to open 2Q2019 –
- Ziopharm abstracts accepted for presentation at ASCO 2019 –

Boston, May 8, 2019 — Ziopharm Oncology, Inc. (Nasdaq: ZIOP), a clinical stage immuno-oncology company developing next generation cell and gene therapies, today announced its financial results for the first quarter ended March 31, 2019, and provided an update on the Company's recent activities.

"We are on track to achieve significant clinical milestones in 2019. All three of our novel immuno-oncology programs are expected to be in the clinic this year," said Laurence Cooper, M.D., Ph.D., CEO of Ziopharm. "We are looking forward to treating patients with solid tumors mid-year with the first non-viral, neoantigen-specific TCR-T cell therapy at the National Cancer Institute (NCI). Our Controlled IL-12 platform is expected to open a phase 2 combination trial with Regeneron's Libtayo® this quarter, and we expect to begin a third-generation *Sleeping Beauty* platform, CD19-specific CAR-T phase 1 trial at MD Anderson Cancer Center in the second half of 2019."

David Mauney, M.D., President of Ziopharm, added, "Our stated focus for the year centers on executional excellence and increasing shareholder value, as we advance our cutting-edge science with each of our programs in the clinic this year. We are pleased to report significant progress with each of these articulated goals and look forward to continuing these efforts throughout the remainder of 2019."

Program Updates

Sleeping Beauty TCR-T Therapies

The Company is using its non-viral gene transfer technology to implement personalized T-cell therapy targeting solid tumors with T-cell receptors, or TCRs. Under a Cooperative Research and Development Agreement (CRADA), which was recently extended through January of 2022, the NCI plans to initiate a Phase 1 clinical trial to treat patients with a variety of metastatic/advanced solid tumors using our *Sleeping Beauty* platform to genetically modify patient-derived T cells to target patient-specific neoantigens.

- **Phase 1 trial for TCR-T cell therapy expected to begin in mid-2019**: This trial is scheduled to begin treating patients in mid-2019 under the direction of Steven A. Rosenberg, M.D., Ph.D., Chief of the Surgery Branch at the NCI.

Sleeping Beauty CAR-T Therapies

Ziopharm is advancing the *Sleeping Beauty* platform for the rapid personalized manufacture (RPM) of CAR-T cells, co-expressing membrane-bound interleukin-15, or mbIL15, with a safety switch, enabling T cells to be infused within two days after genetic modification. This work on our third-generation *Sleeping Beauty* technology is undertaken in collaboration with MD Anderson Cancer Center in the United States and will be accomplished in Greater China through a joint venture, Eden BioCell.

- **Third-generation phase 1 trial for rapid personalized manufacture of *Sleeping Beauty* CD19-specific CAR-T with mbIL15 expected to begin 2H2019:** The Company reaffirms guidance on beginning this trial and treating patients at MD Anderson Cancer Center in the second half of this year. Ziopharm announced in June 2018 that the FDA placed this investigator-led IND on clinical hold and requested additional information demonstrating that the product meet a minimum threshold for overall cell viability. The Company, in partnership with MD Anderson Cancer Center, has made significant progress toward achieving this threshold in manufacturing through improved engineering and cell processing, and expects to be in the clinic at MD Anderson in the second half of this year.
- **Eden BioCell to advance third-generation *Sleeping Beauty* CD19-specific CAR-T for Greater China**: Announced at the end of December 2018, Ziopharm is forming Eden BioCell, a joint venture with partner TriArm Therapeutics, to develop and commercialize *Sleeping Beauty*-generated CD19-specific CAR-T in Greater China. With staffing and planning already under way, Ziopharm looks forward to providing some initial detail on clinical development plans for Eden BioCell later in the year.

Controlled IL-12

Ziopharm is developing its Controlled IL-12 platform, or Ad-RTS-hIL-12 plus veledimex, as a drug to control the production of human interleukin 12 (hIL-12) which activates the immune system to recruit cancer-fighting T cells into solid tumors. In the setting for the treatment of recurrent glioblastoma (rGBM), Ziopharm is advancing Ad-RTS-hIL-12 plus veledimex as a monotherapy and in combination with immune checkpoint inhibitors.

- **Ziopharm abstracts accepted for the 2019 ASCO Annual Meeting:** Titles of accepted abstracts have been released by the American Society of Clinical Oncology for the upcoming Annual Meeting in Chicago (May 31-June 4, 2019):
  - *Evaluation of Controlled IL-12 as Monotherapy in Subjects with Recurrent GBM*. Poster #242, Abstract 2053 in Hall A. (June 2, 2019 8:00 to 11:00 am)
  - *Evaluation of Controlled IL-12 in Combination with PD-1 Inhibitor in Subjects with Recurrent GBM.* Poster #209, Abstract 2020 in Hall A (June 2, 2019 8:00 to 11:00 am). Oral Presentation June 2, 2019 4:30 to 6:00 pm in S404.
- **FDA grants Fast Track status to Controlled IL-12 program:** Ziopharm announced last month that FDA granted Fast Track designation for our Controlled IL-12 program for the treatment of rGBM in adults. The Fast Track program is designed to facilitate the expedited development and review of drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

- **Enrollment completed in phase 1 monotherapy expansion substudy:** Ziopharm announced in February that it rapidly completed enrollment and treated a total of 36 patients in less than six months in a substudy to expand a phase 1 trial evaluating its Controlled IL-12 platform as a monotherapy for the treatment of rGBM. The trial was over-enrolled by 11 patients, which the Company attributes to enthusiasm stemming from encouraging survival and tumor biopsy data. Additional data from the monotherapy studies will be presented through a poster at ASCO 2019.
- **Third cohort has begun in combination substudy with OPDIVO® (nivolumab):** Ziopharm announced in March that it had completed two dosing cohorts in its phase 1 substudy of adult patients with rGBM to evaluate a single dose of Ad-RTS-hIL-12 plus daily veledimex in combination with OPDIVO, an immune checkpoint inhibitor targeting programmed death-1 (PD-1). The Company has begun the third cohort for this study to evaluate the safety and tolerability of this combination regimen, establish optimal dosing of veledimex and OPDIVO, and measure overall patient survival. The Company expects to complete enrollment in the second quarter of 2019. Preliminary data from this trial will be shared at ASCO next month in an oral presentation.
- **Phase 2 combination trial with Regeneron's Libtayo® (cemiplimab-rwlc) expected to open 2Q2019**: The Company, in collaboration with Regeneron Pharmaceuticals, expects to open a phase 2 trial to evaluate Ad-RTS-hIL-12 plus veledimex in combination with Regeneron's PD-1 antibody Libtayo to treat patients with rGBM. The Company expects to enroll approximately 30 patients in this trial.

First Quarter 2019 Financial Results

- Net loss applicable to the common shareholders for the first quarter of 2019 was $13.4 million, or $(0.08) per share, compared to a net loss of $21.1 million, or $(0.15) per share, for the first quarter of 2018. The decreased net loss to common shareholders resulted primarily from the elimination of approximately $5.1 million of dividends to preferred shareholders caused by the forfeiture and return of all of the Company's Series 1 preferred stock in October 2018, along with the changes in research and development expenses and general and administrative expenses noted below.
- Research and development expenses were $9.5 million for the first quarter of 2019, compared to $10.2 million for the first quarter of 2018. The decrease in research and development expenses for the three months ended March 31, 2019 is primarily due to decreased clinical costs related to our cell therapy programs.
- General and administrative expenses were $4.1 million for the first quarter of 2019, compared to $6.2 million for the first quarter of 2018. The decrease in general and administrative expenses for the three months ended March 31, 2019 is primarily due to decreased stock compensation and other employee-related costs.
- The Company ended the quarter with unrestricted cash resources of approximately $51.5 million.
- In addition, a prepayment of approximately $26.4 million remains for programs to be conducted by the Company at MD Anderson Cancer Center under the current Research and Development Agreement.
- The Company believes its current resources will be sufficient to fund its planned operations into the second quarter of 2020.

– Financial Tables Follow –

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

	Three Months Ended March 31, (unaudited)	
	2019	2018
Collaboration revenue	$ —	$ 146
Operating expenses:		
Research and development	9,476	10,183
General and administrative	4,145	6,159
Total operating expenses	13,621	16,342
Loss from operations	(13,621)	(16,196)
Other income (expense), net	187	148
Change in fair value of derivative liabilities	—	28
Net loss	(13,434)	(16,020)
Preferred stock dividends	—	(5,120)
Net Income (loss) applicable to common stockholders	$ (13,434)	$ (21,140)
Basic and diluted net loss per share	$ (0.08)	$ (0.15)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	160,640,859	140,853,120

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

	March 31, 2019	December 31, 2018
Cash and cash equivalents	51,487	61,729
Working capital	65,754	74,802
Total assets	83,503	95,051
Total stockholders' equity (deficit)	74,216	85,564

Conference Call Webcast

The call can be accessed by dialing 1-844-309-0618 (U.S. and Canada) or 1-661-378-9465 (international). The passcode for the conference call is 9185154. To access the live webcast or the subsequent archived recording, 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 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 T-cell receptors (TCRs) to target specific antigens in solid tumors and chimeric antigen receptors (CARs) to target CD19 in blood cancers with the Company's 3rd generation T-cell manufacturing process, rapid personalized manufacture (RPM). 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 Company's business and strategic plans, the availability of cash resources, and the progress and timing of the Company's research and development programs, including the anticipated dates for the initiation, completion and readouts of 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 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. 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.

Company contact:

Chris Taylor
VP, Investor Relations and Corporate Communications
617-502-1881
ctaylor@ziopharm.com