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 8, 2018

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 (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)).

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 8, 2018, 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, 2018. 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 August 8, 2018

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: August 8, 2018

Exhibit 99.1

Ziopharm Oncology Reports Second Quarter 2018 Financial Results and Provides Corporate Update

- Company Focused on Responding to FDA for Third-generation Trial

- NCI to file IND for Sleeping Beauty *Manufactured TCR-T Cell Therapies Targeting Neoantigens in 4Q2018*

- Controlled IL-12 Monotherapy, Combination Studies Advancing

- Changes to Board of Directors and New Staff Illustrate Company Growth Plans

- Company to Host Conference Call Today at 4:30 p.m. ET

BOSTON, Aug. 8, 2018 (GLOBE NEWSWIRE) — Ziopharm Oncology, Inc. (Nasdaq:ZIOP), today announced financial results for the second quarter ended June 30, 2018, and provided an update on the Company's recent activities.

"Our Controlled IL-12 and *Sleeping Beauty* platforms address the major problems in immuno-oncology which are targeting solid tumors and reducing the costs and complexities of T-cell therapies," said Laurence Cooper, M.D., Ph.D., CEO of Ziopharm. "Our team is focused on addressing the FDA's request for more information to lift the clinical hold on the third-generation Phase 1 trial to evaluate CD19-specific T cells produced in under two days using the *Sleeping Beauty* system. We are striving to answer these questions before the end of this year. As a reminder, the hold does not affect our other programs, and indeed our trials infusing CD19-specific CAR-T have resulted in anti-tumor effects."

Dr. Cooper continued, "The team at the National Cancer Institute is on track to submit the IND in the fourth quarter for our Phase 1 trial using the *Sleeping Beauty* platform for the first time to generate T cells that express personalized TCRs to target neoantigens buried within cancer cells. This paves the way for us to develop a personalized approach to targeting solid tumors."

Dr. Cooper added, "Our trials underway using the RheoSwitch® gene switch within Ad-RTS-hIL-12 are evaluating the control of IL-12 as monotherapy and in combination with an immune checkpoint inhibitor in patients with recurrent glioblastoma. We are in advanced discussions with partners that we believe will validate and enhance our approach to brain cancer and additional solid tumors. Lastly, I am delighted to be working with the Board to institute changes to enable Ziopharm to leverage our platforms to solve problems and realize the potential of immunotherapy."

Program Updates

Sleeping Beauty and T-cell Therapies

Using the *Sleeping Beauty* platform to genetically modify cells, the Company is testing chimeric antigen receptor (CAR) T-cell (CAR-T) and T-cell receptor (TCR) T-cell (TCR-T) therapies. These programs are being advanced in collaboration with Precigen Inc., a wholly-owned subsidiary of Intrexon Corporation, The University of Texas MD Anderson Cancer Center, the National Cancer Institute (NCI) and Merck KGaA. Ziopharm has the most clinically-advanced non-viral approach to the genetic modification of T cells, and this approach has the potential to reduce costs of and expand access to this immunotherapy.

Status of IND Application for Phase 1 Trial to Evaluate CD19-targeted CAR-T Therapy: The Company together with its partners at Precigen, Inc. and MD Anderson is focused on responding as soon as possible to the request for more information from the U.S. Food and Drug Administration (FDA) regarding the clinical hold placed on the investigational new drug (IND) application for the third-generation Phase 1 trial to evaluate CD19-specific CAR-T therapies under technology referred to as point-of-care. The FDA has requested additional information relating to chemistry, manufacturing and controls (CMC). Ziopharm is advancing the *Sleeping Beauty* platform towards the very rapid manufacturing of genetically modified CAR+ T cells, co-expressing membrane-bound interleukin-15, or mbIL15, with a kill switch, within two days after genetically modifying T cells from the patient. The Company's guidance on initiating this trial in the second half of this year may be impacted.

Phase 1 Trial of CD19-specific CAR+ T Therapy for B-cell Lymphoid Malignancies: Enrollment and treatment of patients is ongoing at MD Anderson in the second-generation Phase 1 investigator-initiated clinical trial of CAR+ T-cell therapy in patients with refractory leukemias and lymphomas that express CD19. This trial infuses autologous T cells genetically modified with the *Sleeping Beauty* system to express a CD19-specific CAR. Data from this clinical trial showing continued anti-tumor effects will advance understanding of T-cell dosing, CAR design, reducing the time to manufacture T cells and release criteria.

Phase 1 Trial of *Sleeping Beauty*-Modified TCRs to Treat Solid Tumors Expected to Initiate in Fourth Quarter of 2018: Ziopharm, Precigen and the NCI are collaborating under a Cooperative Research and Development Agreement to develop and evaluate adoptive cell therapy for patients with solid tumors. The team at the NCI is developing autologous peripheral blood lymphocytes genetically modified with the *Sleeping Beauty* system to express TCRs that recognize specific immunogenic mutations, or neoantigens, expressed within a patient's solid tumor. The Company guides that this Phase 1 trial, which is being led by and conducted at the NCI, is on track to be initiated in the fourth quarter of 2018.

Phase 1 Trial of CD33-specific CAR+ T Therapy for Acute Myeloid Leukemia (AML): Enrollment and treatment of patients is ongoing at MD Anderson in the Phase 1 investigator-initiated clinical trial of CAR+ T-cell therapy in patients with refractory/recurrent AML that express CD33. This trial infuses autologous T cells genetically modified with lentivirus to express a CD33-specific CAR and a kill switch for elimination of genetically modified cells. Data from this trial are expected to serve as the

basis for evaluating CD33 as a target for further development using non-viral manufacturing of T cells with Ziopharm's point-of-care technology. The Company expects to decide by the end of this year whether or not to transition this CD33-targeted CAR-T therapy to the *Sleeping Beauty* platform.

Collaboration with Merck KGaA: Merck KGaA has selected two targets to pursue using Ziopharm's *Sleeping Beauty* platform technology. Initial proof-of-concept preclinical studies have been completed, and Merck KGaA is evaluating next steps for these targets.

Controlled IL-12

Ziopharm is advancing Ad-RTS-hIL-12 plus veledimex as a gene therapy to treat patients with recurrent glioblastoma (rGBM) as a monotherapy and in combination with an immune checkpoint inhibitor. Ad-RTS-hIL-12 is a replication-incompetent adenoviral vector (Ad) administered via a single injection into the tumor and engineered to conditionally express human interleukin-12 (hIL-12), an immune-stimulatory cytokine that has a demonstrated ability to activate and recruit killer T cells to tumor sites. The expression of hIL-12 is controlled and modulated via the RheoSwitch Therapeutic System® (RTS®) by the small molecule veledimex, an activator ligand which is taken by mouth and crosses the blood-brain barrier. In addition to rGBM, the Company is evaluating Ad-RTS-hIL-12 plus veledimex in additional tumor types in combination with immune checkpoint inhibitors.

First Patient Treated in Combination Trial with OPDIVO® (nivolumab) in rGBM Initiated: Ziopharm announced in June that it treated the first patient in its Phase 1 trial of adult patients with rGBM to evaluate a single dose of Ad-RTS-hIL-12 plus daily veledimex in combination with OPDIVO® (nivolumab), an immune checkpoint inhibitor targeting programmed death-1 (PD-1). The Company expects to enroll up to 18 patients with rGBM in this single-arm study to evaluate the safety and tolerability of this combination regimen, establish optimal dosing of veledimex and nivolumab, and measure overall patient survival. This trial is being conducted at multiple leading brain cancer centers in the United States.

Expansion Substudy Added to Phase 1 Trial in rGBM: Ziopharm initiated an expansion substudy in its Phase 1 trial to evaluate Ad-RTS-hIL-12 plus veledimex as a monotherapy to treat up to 25 patients with rGBM. The Company is adding patients who have not received steroids for four weeks prior to and have not been treated with bevacizumab for their disease to a new cohort receiving a 20mg dose of veledimex. Previously, the Company has shown improvement in survival in patients who received a single injection of Ad-RTS-hIL-12 plus 20mg daily dosing of veledimex. The data from this multi-center U.S. trial will help further understand the benefits of IL-12 as a single-agent.

Phase 1 for Pediatric Tumors Ongoing: Ziopharm is enrolling pediatric patients in its Phase 1 trial of Ad-RTS-hIL-12 with veledimex for the treatment of brain tumors at multiple U.S. sites.

Clinical Data from Breast Cancer and Glioblastoma Studies Presented at ASCO 2018: Updated data from the Company's Phase 1 rGBM study showed median overall survival (mOS) of 12.7 months had been sustained for patients treated with Ad-RTS-hIL-12 plus 20mg of veledimex (n=15) at a mean follow-up time of 12.9 months as of May 2018. This mOS of 12.7 months continues to compare favorably to the 5 to 8 months survival established in historical controls for patients with rGBM. The poster presentation also included biopsy data from rGBM and metastatic breast cancer (mBC) that showed consistent, veledimex dose-dependent production of IL-12 and interferon gamma and a sustained influx of $CD3^{+}CD8^{+}$ cytotoxic T cells. These studies demonstrate that the delivery of IL-12 turns "cold" tumor "hot" which has positive implications for undertaking combination studies with immune checkpoint inhibitors. In the mBC study, disease control rate was 44 percent at week 6 and 22 percent at week 12. Reductions in the diameter of both injected and non-injected lesions was observed and considered evidence of an abscopal effect.

Corporate Update

Ziopharm this week announced changes to its Board of Directors. Scott Tarriff, a member of the Board since 2015, was elected Lead Director, effective immediately, succeeding Sir Murray Brennan, M.D. Both Sir Dr. Brennan and former U.S. Sen. William Wyche Fowler will step down when their terms expire on September 18, 2018, the date of the annual meeting of stockholders. Doug Pagán, CFO of Paratek Pharmaceuticals, and Elan Ezickson, COO and head of corporate development of Scholar Rock, Inc., have been nominated for election to the Board at the Company's annual meeting of stockholders.

The Company today announces the appointment of Mike Moyer as Vice President of Portfolio Strategy, a newly created position in Investor Relations. Mr. Moyer joins Ziopharm from Stifel, where he was the firm's first health care sector desk specialist. Prior to that, he was in institutional sales at Summer Street Research.

Additionally, in June, Catherine Venturini, Ph.D., joined the Company as Vice President and Program Lead for the Controlled IL-12 gene therapy program. Previously, Dr. Venturini spent 10 years in discovery and then development at Bristol-Myers Squibb, managing early and late stage programs, including Abilify, SPRYCEL, EMPLICITI and Yervoy. Most recently, she worked at Biogen, and later its spin off company Bioverativ, where she led clinical development and clinical operations teams.

Second-Quarter 2018 Financial Results

- Net loss applicable to the common shareholders for the second quarter of 2018 was $17.5 million, or $(0.12) per share, compared to a net loss of $17.7 million, or $(0.13) per share, for the second quarter of 2017. The decreased net loss is primarily due to a decrease in total operating expenses during the three months ended June 30, 2018. The decrease in expense was offset by less collaboration revenue realized during the three months ended June 30, 2018, due to the implementation of ASC 606.
- Research and development expenses were $7.5 million for the second quarter of 2018, compared to $10.8 million for the second quarter of 2017. The decrease in research and development expenses for the three months ended June 30, 2018 is primarily due to decreased preclinical activity related to our cell and gene therapy programs.

- General and administrative expenses were $4.9 million for the second quarter of 2018, compared to $3.8 million for the second quarter of 2017. The increase in general and administrative expenses for the three months ended June 30, 2018 is primarily due to contracted outside service costs.
- The Company ended the quarter with unrestricted cash resources of approximately $40.4 million.

In addition, a prepayment of approximately $31.7 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 currently planned operations into the second quarter of 2019.

Conference Call and Slide Webcast

Ziopharm will host a webcast and conference call today, Aug. 8, at 4:30 p.m. ET. 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 1573269. To access the slides and 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 a Boston-based biotechnology company focused on the development of next-generation immunotherapies utilizing gene- and cell-based therapies to treat patients with cancer. In partnership with Precigen Inc., a wholly-owned subsidiary of Intrexon Corporation (NYSE:XON), Ziopharm is focused on the development of two platform technologies designed to deliver safe, effective and scalable cell- and viral-based therapies for the treatment of multiple cancer types: Controlled IL-12 and *Sleeping Beauty* for genetically modifying T cells. The Company's lead asset, Ad-RTS-hIL-12 plus veledimex, has demonstrated in clinical trials the potential to control interleukin-12, leading to an infiltration of T cells that fight brain cancer. The Company also is advancing therapies using *Sleeping Beauty*, a non-viral approach to genetically modify chimeric antigen receptor (CAR^+) and T-cell receptor (TCR^+) T cells, which target specific antigens in blood cancers and neoantigens in solid tumors. *Sleeping Beauty* is designed using the Company's so-called point-of-care technology, a shortened manufacturing process which potentially can be developed as a decentralized manufacturing process based in hospitals. These programs are being advanced in collaboration with Precigen and with MD Anderson Cancer Center, the National Cancer Institute and Merck KGaA, Darmstadt, Germany.

Forward-Looking Statements Disclaimer

This press release contains certain forward-looking statements within the meaning of 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 progress and timing of the development of the Company's research and development programs, including its potential initiation of a first in-human trial using its P-O-C manufacturing process and the timing for the initiation and readouts of its clinical trials. All such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied by, the forward-looking statements. These risks and uncertainties include, but are not limited to: changes in the Company's financial condition and cash needs, funding or other strategic opportunities that become available to the Company, the Company's ability to finance its operations and business initiatives and obtain funding for such activities; whether chimeric antigen receptor T cell (CAR-T) approaches, Ad-RTS-hIL-12, TCR and NK cell-based therapies, or any of other product candidates will advance further in the preclinical research or clinical trial process, including receiving clearance from the FDA to conduct its clinical trials and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether chimeric antigen receptor T cell (CAR-T) approaches, Ad-RTS-hIL-12, TCR and NK cell-based therapies, and the Company's other therapeutic products it develops will be successfully marketed if approved; the strength and enforceability of the Company's intellectual property rights; competition from other pharmaceutical and biotechnology companies; as well as other risk factors contained in the Company's periodic and interim reports filed from time to time with the Securities and Exchange Commission, including but not limited to, the risks and uncertainties set forth in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and subsequent reports that the Company may file with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and the Company does not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

Ziopharm Oncology, Inc.
Statements of Operations
(in $ thousands except share and per share data)
Unaudited

	Three Months Ended June 30	
	2018	**2017**
Collaboration revenue	$ —	$ 1,597
Operating expenses:		
Research & Development	7,489	10,831
General and Administrative	4,889	3,780
Total operating expenses	12,378	14,611
Loss from operations	(12,378)	(13,014)
Other income (expense), net	164	86
Change in fair value of derivative liabilities	183	66
Net loss	(12,031)	(12,862)
Preferred stock dividends	(5,462)	(4,865)
Net loss applicable to common stockholders	$ (17,493)	$ (17,727)
Basic and diluted net loss per share	$ (0.12)	$ (0.13)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	141,017,898	135,630,210

Ziopharm Oncology, Inc.
Balance Sheet Data
(in thousands)
(Unaudited)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	40,404	70,946
Working capital	43,679	69,927
Total assets	76,383	105,606
Total stockholders' (deficit)	(139,235)	(96,806)

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