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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 9, 2016**

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**ZIOPHARM Oncology, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**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)

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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)).
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**Item 2.02      Results of Operations and Financial Condition**

On August 9, 2016, 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, 2016. 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 9, 2016

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: Vice President Finance, Chief Accounting Officer and Treasurer

Date: August 9, 2016

**INDEX OF EXHIBITS**

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## **ZIOPHARM Oncology, Inc.**

### **ZIOPHARM Reports Second-Quarter 2016 Financial Results and Provides Update on Recent Activities**

*- Company to Host Conference Call at 4:30 PM ET Today -*

**BOSTON, MA – August 9, 2016** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today announced financial results for the second quarter ended June 30, 2016, and provided an update on the Company's recent activities.

“ZIOPHARM had a very productive first half, with the achievement of pipeline and corporate milestones across the breadth of our portfolio and the advancement of our goal to position the company at the forefront of those harnessing the immune system to target cancer,” said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of ZIOPHARM Oncology. “Central to this effort, we were pleased to have amended the terms of our collaboration with Intrexon to facilitate the commercialization of our immunotherapy assets. The benefit of this new structure is expected to be first realized with our gene therapy Ad-RTS-hIL-12 + veledimex program, which remains on track to move into a registrational trial in advanced glioblastoma in 2017.”

Dr. Cooper added: “As we progress through the remainder of 2016, we will continue to work with our collaborators, including Intrexon Corporation and the MD Anderson Cancer Center, to advance new therapies into the clinic. We look forward in 2016 to seeing six clinical trials exploring immuno-oncology approaches and combinations, in addition to preclinical projects advancing towards the clinic. As these programs mature, we expect to see proof-of-concept clinical data that will drive value for all of our stakeholders.”

#### **Corporate and Program Updates**

##### Corporate

**Amended Exclusive Channel Collaborations with Intrexon to Improve Alignment as Programs Advance through Development.** In June, ZIOPHARM and Intrexon Corporation (NYSE:XON) announced amendments to their Exclusive Channel Collaborations (ECCs) in the fields of oncology and graft-versus-host-disease (GvHD) to improve alignment between both companies as ZIOPHARM broadens its pipeline and advances multiple therapeutic programs in the clinic.

Under the terms of the amendments:

- Operating profit rates payable to Intrexon from ZIOPHARM on products developed under its two existing collaborations will be reduced from 50% to 20%. This reduction will not apply to royalties or other payments made with respect to the companies' existing collaboration with Merck Serono, the biopharmaceutical business of Merck KGaA;
- Economics from any future sublicensing arrangements with potential third party collaborators will remain evenly split.

In consideration of the amendments, ZIOPHARM has issued shares of a new class of preferred stock that carries an initial stated value of \$120 million and a monthly dividend of 1%, payable in additional preferred shares. Only upon the first approval of a product in the United States or upon certain fundamental transactions, such as a change of control of ZIOPHARM, the preferred shares issued to Intrexon will be converted into ZIOPHARM common stock equal to the aggregate stated value divided by the volume weighted average closing price of ZIOPHARM's common stock over the 20 trading days ending on the date that the product approval or such transaction is announced.

### Gene Therapies

Ad-RTS-hIL-12 + veledimex is a gene therapy candidate for the controlled expression of interleukin 12 (IL-12), a critical protein for stimulating an anti-cancer immune response, using the RheoSwitch Therapeutic System® (RTS®) gene switch. ZIOPHARM is currently enrolling patients in two studies of Ad-RTS-hIL-12 + veledimex: a multi-center Phase 1 study in patients with recurrent or progressive glioblastoma multiforme (GBM), an aggressive form of brain cancer, and a Phase 1b/2 study for the treatment of patients with locally advanced or metastatic breast cancer following standard chemotherapy.

- **Presented Clinical Data Highlighting Favorable Interim Survival Results in Phase 1 Study of Ad-RTS-hIL-12 + Veledimex in Brain Cancer.** ZIOPHARM presented data from its Phase 1, multi-center dose-escalation study of patients with recurrent high-grade gliomas at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting held June 3-7, 2016 in Chicago and updated at an American Society of Hematology Workshop on Genome Editing in Washington D.C on July 14, 2016. These data demonstrate promising early activity in this medically fragile patient population, with a median overall survival that has not been reached with 11 of 14 patients alive and in follow up, and a median follow up of 8 months with 6 patients out of 7 patients alive in the study's first dose cohort (20mg veledimex). The study also showed that IL-12 in the bloodstream was found to be proportional to the amount of veledimex administered, demonstrating that this orally-delivered activator crossed the blood brain barrier to activate the IL-12 gene programming deposited in the tumor and turned on the RheoSwitch® technology in a dose-dependent manner. In June, ZIOPHARM announced the successful completion of enrollment in the first and second dosing cohorts (40mg veledimex) of the study, as well as the initiation of enrollment in a third cohort (30mg veledimex).
- **Preclinical Studies Combining Ad-RTS-IL-12 + Veledimex and Immune Checkpoint Inhibitors in Brain Tumor Models Presented at ASGCT, Combination Study Expected to Initiate in 2016.** In an oral presentation, ZIOPHARM presented data from preclinical studies of Ad-RTS-IL-12 + veledimex

combined with immune checkpoint inhibitors (iCPI) in glioblastoma (GBM) mouse models at the 2016 Meeting of the American Society of Gene and Cell Therapy (ASGCT), which took place May 4-7, 2016 in Washington, D.C. Results demonstrated that survival of mice treated with Ad-RTS-IL-12 + veledimex and anti-PD-1 therapy was superior to either treatment alone, with a combination showing 100% survival. Because Ad-RTS-IL-12 and anti-PD-1 are clinically available, these data provide impetus for evaluating this combination immunotherapy in humans. ZIOPHARM plans to initiate a combination study in 2016.

### Adoptive Cell Therapies

ZIOPHARM is developing various immuno-oncology programs, including chimeric antigen receptor T-cell (CAR-T), T-cell receptor (TCR), and natural killer (NK) adoptive cell-based therapies. These programs are being advanced in collaboration with Intrexon, MD Anderson Cancer Center, and Merck Serono (CAR-T only).

- **Announced Plans for Phase I Clinical Trial with CD33 CAR-T Cell Therapy.** In July, ZIOPHARM announced plans for a Phase I adoptive cellular therapy clinical trial utilizing autologous T cells transduced with lentivirus to express a CD33-specific chimeric antigen receptor (CAR) in patients with relapsed or refractory acute myeloid leukemia (AML). The trial is based on preclinical studies, including in vitro data demonstrating that lentiviral-transduced CAR-T cells targeting CD33 exhibit specific killing activity for CD33<sup>+</sup> AML cells and a proof-of-concept study utilizing an in vivo mouse model for AML, which showed that these CAR-T cells were able to eliminate disease and significantly enhance survival as compared to control groups. These positive preclinical results indicate biological activity and are suggestive of potential therapeutic effect for the treatment of AML.
- **Announced Publication of First-In-Human Trials using Non-Viral *Sleeping Beauty* System to Express CD19-Specific CAR in T cells in *Journal of Clinical Investigation*.** In August, ZIOPHARM announced the publication of data highlighting the benefits of using the non-viral *Sleeping Beauty* (SB) system to genetically modify T cells to express a chimeric antigen receptor (CAR) for use against leukemias and lymphomas. The article, titled “Phase I trials using Sleeping Beauty to generate CD19-specific CAR T cells,” was published in the *Journal of Clinical Investigation* (doi:10.1172/JCI86721), and is available online [here](#).

The paper describes results for 26 patients with multiply relapsed B-lineage acute lymphoblastic leukemia (ALL, n=17) or B-cell non-Hodgkin lymphoma, (NHL, n=9) who were enrolled in two investigator-initiated clinical trials at the University of Texas MD Anderson Cancer Center infused with SB-modified T cells after autologous (n=7) or allogeneic (n=19) hematopoietic stem-cell transplantation (HSCT). Although the primary objective of these trials was not to establish efficacy, the recipients’ outcomes are encouraging, with apparent doubling of survivals compared to historical controls which is attributed to the persistence of the infused T cells. Additionally, by infusing a CD19-specific CAR T cells to target minimal residual disease after autologous and allogeneic HSCT, the approach may improve tolerability by avoiding cytokine storm.

## Milestones

ZIOPHARM achieved and expects the following milestones to occur in 2016:

- Intra-tumoral IL-12 RheoSwitch® programs:
  - Clinical update presented from the Company's Phase 1 study of GBM at the Annual Meeting of the American Society of Clinical Oncology
  - Update on Phase 1/2 study in Breast Cancer with standard of care presented at ASCO
  - Pre-clinical data presented at the American Society of Cell and Gene Therapy (ASGCT) Annual Meeting for combining with checkpoint inhibitor therapy (anti PD-1)
  - Initiate combination study of Ad-RTS-hIL-12 with anti PD-1
- CAR+ T programs:
  - Continuation of second generation CD19 CAR+ T clinical study
  - Initiate a CAR+ T clinical study for CD33
  - Preclinical data presented at ASGCT for shortening the time of *ex vivo* manufacture of SB-modified T cells
  - Initiate CAR+ T-cell preclinical studies for other hematological malignancies and solid tumors
- TCR-T programs
  - Initiate TCR-modified T-cell preclinical studies
- NK cell programs
  - Initiate a Phase 1 study of off-the-shelf NK cells for AML
- GvHD programs
  - Initiate preclinical studies
- Pediatric programs
  - Pre-clinical data to be presented in the fall with intra-tumoral IL-12 under RheoSwitch® control for brain tumor

The Company is also evaluating additional potential preclinical candidates and continuing discovery efforts aimed at identifying other potential product candidates under its Exclusive Channel Agreement with Intrexon. In addition, the Company may seek to enhance its pipeline in immuno-oncology through focused strategic transactions, which may include acquisitions, partnerships and in-licensing activities.

## **Conference Call**

ZIOPHARM will host a conference call and webcast slide presentation today, August 9, 2016, at 4:30 pm ET. The call can be accessed by dialing 1-844-309-0618 (U.S. and Canada) or 661-378-9465 (international). The passcode for the conference call is 58685274. To access the slide and live audio webcast, or the subsequent archived recording, visit the "Investors & Media" section of the ZIOPHARM website at [www.ziopharm.com](http://www.ziopharm.com). The webcast will be recorded and available for replay on the Company's website for two (2) weeks.



## Second-Quarter 2016 Financial Results

- Net loss for the second quarter of 2016 was \$131.2 million, or \$(1.01) per share, compared to a net loss of \$14.2 million, or \$(0.11) per share, for the second quarter of 2015. The primary driver of the increase was the amendments to the Company's Exclusive Channel Collaborations in the fields of oncology and graft-versus-host-disease disclosed above. The Company recorded a non-cash charge of \$119.1 million, or \$(0.91) per share for the fair value of the Series 1 preferred stock that was issued on July 1, 2016. Additionally, the Company recognized approximately \$1.7 million in revenue during the quarter in comparison with \$0.3 million in revenue in 2015 as a result of revenue recognized under the Ares Trading Agreement.
- Research and development expenses were \$129.2 million for the second quarter of 2016 compared to \$7.4 million for the second quarter of 2015. The increase in research and development expenses for the quarter is primarily due to the non-cash charge of \$119.1 million for the fair value of the Series 1 preferred stock that was issued on July 1, 2016.
- General and administrative expenses were \$3.7 million for the second quarter of 2016 compared to \$7.1 million for the second quarter of 2015. The decrease was primarily due to a reduction in employee related costs in 2016.
- The Company ended the quarter with cash and cash equivalents of approximately \$109.0 million, which the Company believes will be sufficient to fund its currently planned activities into the fourth quarter of 2017.

### About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a Boston, Massachusetts-based biotechnology company employing novel gene expression, control and cell technologies to deliver safe, effective and scalable cell- and viral-based therapies for the treatment of cancer. The Company's immuno-oncology programs, in collaboration with Intrexon Corporation (NYSE:XON) and the MD Anderson Cancer Center, include chimeric antigen receptor T cell (CAR-T) and other adoptive cell-based approaches that use non-viral gene transfer methods for broad scalability. The Company is advancing programs in multiple stages of development together with Intrexon Corporation's RheoSwitch Therapeutic System® technology, a switch to turn on and off, and precisely modulate, gene expression in order to improve therapeutic index. The Company's pipeline includes a number of cell-based therapeutics in both clinical and preclinical testing which are focused on hematologic and solid tumor malignancies.

### Forward-Looking Safe-Harbor Statement:

This press release contains certain forward-looking information about ZIOPHARM Oncology, Inc. that is intended to be covered by the safe harbor for "forward-looking statements" provided by 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 plans and expectations regarding its securities offerings, fundraising activities and financial strategy, the progress, timing and results of preclinical and clinical trials involving the Company's drug candidates, and the progress

of the Company's research and development programs. All of 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: our ability to finance our 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 our other therapeutic candidates will advance further in the pre-clinical or clinical trials process 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 our other therapeutic products will be successfully marketed if approved; the strength and enforceability of our intellectual property rights; competition from other pharmaceutical and biotechnology companies; and the other risk factors contained in our periodic and interim SEC reports filed from time to time with the Securities and Exchange Commission, including but not limited to, our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and our Quarterly Report for the quarter ended June 30, 2016. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do 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.

#### **Trademarks**

RheoSwitch Therapeutic System® and RTS® technology are registered trademarks of Intrexon Corporation.

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

	Three Months Ended June 30,	
	2016	2015
Revenue	\$ 1,697	\$ 272
Operating expenses:		
Research and development, including cost of contracts	129,228	7,424
General and administrative	3,711	7,073
Total operating expenses	132,939	14,497
Loss from operations	(131,242)	(14,225)
Other income (expense), net	42	14
Net loss	\$ (131,200)	\$ (14,211)
Basic and diluted net loss per share	\$ (1.01)	\$ (0.11)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	130,385,077	128,413,417

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

	<u>June 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Cash and cash equivalents	109,004	140,717
Working capital	110,674	134,398
Total assets	128,012	153,724
Total stockholders' equity (deficit)	(51,990)	87,371

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