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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): November 2, 2015**

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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)

**84-1475672**  
(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 November 2, 2015, ZIOPHARM Oncology, Inc. issued a press release announcing its financial condition and results of operations for the three months ended September 30, 2015. 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 November 2, 2015

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: November 2, 2015

**INDEX OF EXHIBITS**

**Exhibit No.**

**Description**

99.1 Press Release of ZIOPHARM Oncology, Inc. dated November 2, 2015



## ZIOPHARM Oncology, Inc.

### ZIOPHARM Reports Third-Quarter 2015 Financial Results and Recent Activities

**BOSTON, MA – November 2, 2015** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today announced financial results for the third quarter ended September 30, 2015, and provided an update on the company's recent activities.

“The third quarter saw an important expansion of our pipeline with the signing of a new Exclusive Channel Collaboration with our longtime partner Intrexon to include immunotherapies for the treatment of graft-versus-host-disease, or GvHD,” said Laurence Cooper, M.D., Ph.D., Chief Executive Officer of ZIOPHARM. “This adds to our research programs with Intrexon in virotherapies, T-cell therapies and natural killer cell therapies for the treatment of cancer, all of which are advancing in the lab and clinic. We look forward to presenting a variety of data at scientific meetings before the end of this year.”

#### Recent Highlights

##### Ad-RTS-hIL-12

Ad-RTS-hIL-12 is a gene therapy candidate for the controlled expression of interleukin 12 (IL-12), a critical protein for stimulating an anti-cancer T cell immune response, using the RheoSwitch Therapeutic System® (RTS®) gene switch. ZIOPHARM is currently enrolling patients in two studies of Ad-RTS-hIL-12: a Phase 1b/2 study for the treatment of patients with locally advanced or metastatic breast cancer following standard chemotherapy and a multi-center Phase 1 study in patients with recurrent or progressive glioblastoma multiforme, a form of brain cancer. The Company expects that early results from each study will be presented at scientific meetings prior to year's end.

In September, ZIOPHARM announced the presentation of preclinical and clinical data from the Company's Ad-RTS-IL-12 program in various malignancies at the CRI-CIMT-EATI-AACR Inaugural International Cancer Immunotherapy Conference in New York City.

These included a presentation highlighting additional evidence of systemic immune activation with Ad-RTS-hIL-12 and veledimex in advanced melanoma and breast cancer patients. Among other findings, treatment with Ad-RTS-hIL-12 and veledimex in patients with melanoma was found to increase the immune cytokine IL-12 and downstream cytokines, interferon gamma (IFN-g), interferon gamma-inducible protein 10 (IP-10) and interleukin 10 (IL-10), resulting in a significant increase in tumor infiltrating lymphocytes both locally, in injected lesions, and systemically, in non-injected lesions. These data provide clinical evidence of an abscopal response, in which local treatment affects other tumor sites at a distance, and confirm that localized therapy can lead to beneficial systemic anti-tumor effects.

A second presentation demonstrated the anti-tumor effects and tolerability of Ad-RTS-mIL-12 in mouse models of glioblastoma (brain cancer), colon cancer and melanoma. These data showed

dose-related increases in veledimex in both plasma and brain tissue, leading to a corresponding elevation in expression of IL-12 mRNA. Ad-RTS-mIL-12 and veledimex also demonstrated systemic memory upon rechallenge in multiple syngeneic mouse models, providing further evidence of systemic anti-tumor immunity elicited by Ad-RTS-mIL-12.

ZIOPHARM announced in July 2015 that the U.S. Food and Drug Administration granted Orphan Drug Designation for Ad-RTS-hIL-12 and veledimex in the treatment of patients with malignant glioma. The FDA's Office of Orphan Products grants orphan drug status to support development of medicines for underserved patient populations or rare disorders affecting fewer than 200,000 people in the U.S. Orphan Drug Designation provides eligibility for a seven-year period of market exclusivity in the United States after product approval, an accelerated review process, accelerated approval where appropriate, grant funding, tax benefits and an exemption from user fees.

#### 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 Intrexon, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, and the MD Anderson Cancer Center.

ZIOPHARM expects that early results from its adoptive cell therapy programs, including data highlighting the *Sleeping Beauty* non-viral gene transfer technology, will be presented to the medical and scientific community prior to yearend.

ZIOPHARM announced in September the publication of a preclinical study in *Cancer Research*, a journal of the American Association for Cancer Research, demonstrating the preferential targeting of solid tumor cells over healthy cells using engineered chimeric antigen receptor (CAR) T cells. The publication described how tuning the binding affinity of CARs to activate T cells based on the density of EGFR expression allows for targeting of cancer cells with high levels of EGFR, while sparing normal cells with low levels of EGFR. The study demonstrates an approach for translating the effects of adoptive CAR T-cells from liquid to solid tumors.

#### GvHD

In September, Intrexon Corporation announced that it has formed a new Exclusive Channel Collaboration with ZIOPHARM for the treatment and prevention of graft-versus-host disease (GvHD). GvHD is a major complication of allogeneic hematopoietic stem-cell transplantation which significantly impairs the quality of life and survival of many recipients, and is unaddressed by existing treatments, which have limited efficacy and increased toxicity. The collaboration will focus on addressing the underlying pathologies of GvHD through engineered cell platforms to express and controlled delivery of interleukin-2 (IL-2), a cytokine critical for modulation of the immune system. The companies plan to employ two treatment approaches: infusion of regulatory T cells (Tregs) conditionally expressing IL-2 utilizing Intrexon's proprietary gene control approaches such as its RheoSwitch® platform; and deployment of orally-delivered microbe-based ActoBiotics® therapeutics expressing IL-2 to modulate immune function.

Under the terms of the agreement, Intrexon is to receive a technology access fee of \$10 million in cash and reimbursement for all research and development costs. The agreement also provides for equal sharing of operating profits.

## Corporate

In September, ZIOPHARM announced the appointment of Scott Tarriff to the Company's Board of Directors. Mr. Tarriff, who serves as President, Chief Executive Officer and a Director of Eagle Pharmaceuticals, brings more than 25 years of pharmaceutical industry experience to ZIOPHARM.

### **Third-Quarter 2015 Financial Results**

- Net loss for the third quarter of 2015 was \$18.2 million, or \$(0.14) per share, compared to a net loss of \$6.1 million, or \$(0.06) per share, for the third quarter of 2014. Included in the loss for the third quarter of 2014 was non-cash income of \$5.8 million, or \$(0.06) per share for the change in fair value of warrants.
- Research and development expenses were \$17.0 million for the third quarter of 2015 compared to \$9.7 million for the third quarter of 2014. The increase in research and development is due to a \$10.0 million charge for in-process research and development with Intrexon for GvHD, and of \$4.3 million related to CAR-T programs. These increases were offset by \$5.7 million in savings related to discovery and nonclinical activities, \$625 thousand in clinical study costs related to small molecule programs and \$775 thousand savings in payroll, employee related and other expenses.
- General and administrative expenses were \$3.1 million for the third quarter of 2015 compared to \$2.8 million for the third quarter of 2014. The increase of \$0.3 million in general and administrative expenses is primarily attributable to non-cash equity compensation and other employee related expenses.
- The Company ended the quarter with cash and cash equivalents of approximately \$163.8 million. Given current development plans, the Company anticipates that current cash resources will be sufficient to fund our planned operations into the first quarter of 2018.

### **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-based therapies for the treatment of cancer. The Company's synthetic 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 kill switch and 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 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: whether chimeric antigen receptor T cell (CAR T) approaches, Ad-RTS-IL-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-IL-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, 2014, and our Quarterly Reports on Form 10Q for the quarters ended March 31, 2015, June 30, 2015 and September 30, 2015. 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® (RTS®) technology is a registered trademark of Intrexon Corporation.



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

	Three Months Ended September 30,	
	2015	2014
Revenue	\$ 1,869	\$ 633
Operating expenses:		
Research and development	16,970	9,733
General and administrative	3,065	2,842
Total operating expenses	20,035	12,575
Loss from operations	(18,166)	(11,942)
Other income (expense), net	(4)	2
Change in fair value of warrants	—	5,847
Net loss	\$ (18,170)	\$ (6,093)
Basic and diluted net loss per share	\$ (0.14)	\$ (0.06)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	129,732,356	100,428,520

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

	September 30, 2015	December 31, 2014
Cash and cash equivalents	163,843	42,803
Working capital	142,853	33,261
Total assets	173,361	45,237
Total stockholders' equity	93,841	33,841

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**Contact:**

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