

**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): **June 6, 2011**

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**ZIOPHARM Oncology, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-33038**  
(Commission File Number)

**84-1475672**  
(IRS Employer  
Identification No.)

**1180 Avenue of the Americas  
19<sup>th</sup> Floor  
New York, NY**  
(Address of Principal Executive Offices)

**10036**  
(Zip Code)

**(646) 214-0700**  
(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 8.01**      **Other Events**

On June 6, 2011, ZIOPHARM Oncology, Inc. (the "Company") issued a press release disclosing clinical results from the Company's Phase Ib study of DC-RTS-IL-12, also referred to as ZIN-CTI-001, presented by Douglas J. Schwartzentruber, MD, FACS, of the Indiana University Health Goshen Center for Cancer Care, at the 2011 Annual Meeting of the American Society of Clinical Oncology in Chicago, IL.

A copy of the above referenced press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01**      **Financial Statements and Exhibits.**

(d)      Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated June 6, 2011

**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/ Richard Bagley

Name: Richard Bagley

Title: President, Chief Operating Officer and Chief Financial Officer

Date: June 6, 2011

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**INDEX OF EXHIBITS**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press release dated June 6, 2011

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## **ZIOPHARM Oncology, Inc.**

**ZIOPHARM Announces Initial Positive Data Presented at 2011 ASCO Annual Meeting from First-Ever Treatment Demonstrating Small Molecule-Controlled Production of Anticancer Protein in Humans**

*Treatment with ZIN-CTI-001 Well Tolerated, Demonstrates Substantial Disease Control*

*Intra-tumoral Generation of IL-12 and Associated Proteins Leads to Systemic Anti-Melanoma T-cell Immunity*

**CHICAGO, IL (June 6, 2011)** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today that Douglas J. Schwartzentruber, MD, FACS, of the Indiana University Health Goshen Center for Cancer Care, presented initial positive clinical results from the first-ever treatment demonstrating control over transgene encoding of a therapeutic anticancer protein in humans using a small molecule activator ligand. These results were presented at the 2011 Annual Meeting of the American Society of Clinical Oncology (ASCO) being held June 3 – 7, in Chicago, IL.

The Phase Ib study of DC-RTS-IL-12, also referred to as ZIN-CTI-001, in patients with advanced melanoma, entitled “Immunotherapy of advanced melanoma by intra-tumoral injections of autologous, purified dendritic cells transduced with gene construct of interleukin-12, with dose-dependent expression under the control of an oral activator ligand,” was presented in the Developmental Therapeutics – Clinical Pharmacology and Immunotherapy Poster Session (Poster #1A, Abstract #2540).

ZIN-CTI-001, the Company’s most advanced synthetic biology product candidate, employs autologous dendritic cells (DC) transduced with a controllable gene switch, and a gene for expressing Interleukin-12 (IL-12), a potent anticancer protein. Ten patients with advanced melanoma have been enrolled in the study of a range of doses of an orally administered activator ligand (AL). ZIN-CTI-001 injected intratumorally, then “switched on” by the AL, demonstrated a balance of tolerability (primarily mild to moderate adverse events) and response (a substantial disease control rate of 50% among evaluable patients (n=8)). The data also showed a correlation between T-cell immune responses and clinical outcome, a desired outcome with the highly focused use of IL-12, with limited adverse events (AEs) and one significant adverse event (SAE) that completely resolved.

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“IL-12, an important regulator of immune response to cancer and other diseases, is a protein whose use as a recombinant protein therapy has to date been limited by substantial systemic toxicity,” said Dr. Schwartzentruber, lead author of the study. “By using a small-molecule activator ligand to ‘switch on’ an intracellularly delivered gene that produces IL-12 right in the tumor, we have much more control over IL-12’s potent antitumor effects. These data, the first in humans to test this novel system, have yielded encouraging results that include disease control predictive of clinical benefit, and warrant further clinical study.”

John M. Kirkwood, MD, of the University of Pittsburgh Cancer Institute and co-author of the study, added, “These data demonstrate the clinical application of a new and promising technology, enabling the controlled expression of therapeutic proteins manufactured within the body. This study of intratumoral generation of IL-12 and associated proteins that may augment anti-melanoma T-cell immunity in the tumor will be important to validate in larger studies.”

### **Results in Detail**

The study enrolled ten patients (median age 61) with unresectable Stage III or IV melanoma. Primary endpoints were safety and tolerability. Secondary endpoints included response, single dose and steady-state pharmacokinetics of the oral AL, an analysis of IL-12 and associated proteins, and cellular immune response (anti-melanoma and immunoregulatory cells) in blood and tissue biopsies. Patients were treated with autologous ZIN-CTI-001 cells ( $\sim 5 \times 10^7$ ) injected into accessible tumors, in combination with AL (escalating between 0.6 – 200 mg daily) administered orally for 14 days per treatment cycle ( $\leq$  five (5) treatment cycles). Safety, mechanism of action (genomic and immunologic) and clinical responses (CT evaluation by RECIST) were assessed.

Among eight evaluable patients, partial or complete regression of injected and some uninjected lesions was observed by CT in three patients, with one patient having RECIST PR of  $>11$  months and three patients demonstrating stable disease by RECIST, for an overall disease control rate of 50%. Further, the results confirmed that intratumoral generation of IL-12 and associated proteins lead to systemic anti-melanoma T cell immunity including cytotoxic CD8<sup>+</sup> T cells and TH1 CD4<sup>+</sup> cells, without any evidence of increased T regulatory cells or myeloid-derived suppressor cells.

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Treatment was generally well tolerated, and maximum tolerated dose (MTD) has not yet been reached. AEs were mild to moderate, with one to two (1-2) patients each experiencing nausea, vomiting, anorexia, arthralgia, fever or chills. One SAE was reported 18 hours after treatment onset with 60 mg AL + ZIN-CTI-001, and included diarrhea, followed by hypotension and reversible acute renal failure, which completely resolved.

#### **About ZIOPHARM Oncology, Inc.:**

ZIOPHARM Oncology is a biopharmaceutical company engaged in the development and commercialization of a diverse portfolio of cancer therapeutics. The Company is currently focused on several clinical programs.

Palifosfamide (Zymafos™ or ZIO-201) is a novel DNA cross-linker in class with bendamustine, ifosfamide, and cyclophosphamide. ZIOPHARM is currently enrolling patients in a randomized, double-blinded, placebo-controlled Phase III trial with palifosfamide administered intravenously for the treatment of metastatic soft tissue sarcoma in the front-line setting. The company is also currently conducting a Phase I intravenous study of palifosfamide in combination with standard of care addressing small cell lung cancer and an oral form of the drug for treatment of solid tumors is currently in the advanced preclinical stage of development.

Darinaparsin (Zinapar™ or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) being developed intravenously for the treatment of relapsed peripheral T-cell lymphoma likely with a two-stage potentially pivotal study expected to begin in late 2011. An oral form is in a Phase I trial in solid tumors.

Indibulin (Zybulin™ or ZIO-301) is a novel, oral tubulin binding agent that is expected to have several potential benefits including oral dosing, application in multi-drug resistant tumors, no neuropathy and a quite tolerable toxicity profile. It is currently being studied in Phase I/II in metastatic breast cancer.

ZIOPHARM is also pursuing the development of novel DNA-based therapeutics in the field of cancer pursuant to an exclusive channel partnership with Intrexon Corporation. The partnership includes two existing clinical-stage product candidates, the first of which is in a Phase Ib study and the second is currently the subject of an Investigational New Drug (IND) application filed with the U.S. Food and Drug Administration.

ZIOPHARM's operations are located in Boston, MA and Germantown, MD with an executive office in New York City. Further information about ZIOPHARM may be found at [www.ziopharm.com](http://www.ziopharm.com).

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**About Intrexon Corporation:**

Intrexon Corporation is a privately held synthetic biology company that employs modular DNA control systems to enhance capabilities, improve safety and lower cost in human therapeutics, protein production, industrial products, animal sciences and agricultural biotechnology. The company's advanced transgene engineering platform enables Better DNA™ by combining breakthroughs in DNA control systems with corresponding advancements in modular transgene design, assembly and optimization. The company is currently using these advanced capabilities to undertake foremost challenges across the spectrum for biological applications. More information about the company is available at [www.DNA.com](http://www.DNA.com).

**Forward-Looking Safe Harbor Statement:**

This press release contains forward-looking statements for ZIOPHARM Oncology, Inc. that involve risks and uncertainties that could cause ZIOPHARM Oncology's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Among other things, there can be no assurance that any of ZIOPHARM Oncology's development efforts relating to its product candidates will be successful, or such product candidates will be successfully commercialized. Other risks that affect forward-looking information contained in this press release include the possibility of being unable to obtain regulatory approval of ZIOPHARM Oncology's product candidates, the risk that the results of clinical trials may not support ZIOPHARM Oncology's claims, the risk that pre-clinical or clinical trials will proceed on schedules that are consistent with ZIOPHARM Oncology's current expectations or at all, risks related to ZIOPHARM Oncology's ability to protect its intellectual property and its reliance on third parties to develop its product candidates, risks related to the sufficiency of existing capital reserves to fund continued operations for a particular amount of time and uncertainties regarding ZIOPHARM Oncology's ability to obtain additional financing to support its operations thereafter, as well as other risks regarding ZIOPHARM Oncology's that are discussed under the heading "Risk Factors" in ZIOPHARM Oncology's filings with the United States Securities and Exchange Commission. Forward-looking statements can be identified by the use of words such as "may," "will," "intend," "should," "could," "can," "would," "expect," "believe," "estimate," "predict," "potential," "plan," "is designed to," "target" and similar expressions. ZIOPHARM Oncology assumes no obligation to update these forward-looking statements, except as required by law.

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