

**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): **October 28, 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 October 28, 2011, the Company issued a press release announcing the presentation of preclinical data with palifosfamide (Zymafos™ or ZIO-201) in a pediatric sarcoma model. The data was detailed in an oral session of the 2011 meeting of the combined Connective Tissue Oncology Society (CTOS) Musculoskeletal Tumor Society (MSTS), being held October 26 – 29, 2011 in Chicago, IL.

A copy of the above referenced press release is filed as Exhibit 99.1 to this Current Report of Form 8-K.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated October 28, 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: October 28, 2011

**INDEX OF EXHIBITS**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press Release of the Company dated October 28, 2011



## ZIOPHARM Oncology, Inc.

### ZIOPHARM Presents Promising Preclinical Pediatric Sarcoma Data with Oral and IV Palifosfamide at the 2011 CTOS/MSTS Meeting

**NEW YORK, NY (October 28, 2011)** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a drug development company employing small molecule and synthetic biology approaches to cancer therapy, today announced the presentation of promising preclinical data with palifosfamide (Zymafos™ or ZIO-201) in a pediatric sarcoma model. The data was detailed in an oral session of the 2011 meeting of the combined Connective Tissue Oncology Society (CTOS) Musculoskeletal Tumor Society (MSTS), being held October 26 – 29, 2011 in Chicago, IL.

The presentation, entitled “Palifosfamide, a Bifunctional DNA Alkylator, Inhibits Growth of Pediatric Sarcoma Xenografts Across a Wide Dose Range Following Oral and Parenteral Dosing,” addressed, among other findings, the impact of palifosfamide activity in the presence of overexpression of aldehyde dehydrogenase (ALDH), an enzyme thought to confer resistance to alkylators like cyclophosphamide and ifosfamide. The authors reported that palifosfamide, a bi-functional DNA-alkylator in class with ifosfamide, cyclophosphamide and bendamustine, did not exhibit ALDH resistance. This important finding, combined with the use of oral administration and a potentially favorable toxicity profile, are particularly relevant for the pediatric population.

*In vivo* modeling for the study was conducted in the Cancer Therapeutics Laboratory of the Alfred I. DuPont Hospital for Children. The authors included E. Anders Kolb, M.D., Director, Blood and Bone Marrow Transplantation and Head, Cancer Therapeutics Laboratory as lead author and Richard Gorlick, M.D., Vice Chairman of Pediatrics at Albert Einstein College and Chairman of the Children’s Oncology Group (COG) Bone Sarcoma Committee as senior author. Results showed that orally administered palifosfamide was found to have broad *in vivo* preclinical activity comparable to parenteral administration in an osteosarcoma model. This activity was measured by tumor growth delay, relative tumor volume (RTV) and event-free survival across all doses. Investigators also found palifosfamide active in xenografts with overexpressed levels of ALDH. Overexpression of ALDH is present in diverse tumor types including breast cancer, colon cancer, pancreas cancer, Ewing’s sarcoma and other cancers, and is a marker of cancer stem cells. Ongoing testing of dose and schedule in both sarcoma and breast cancer models will define future clinical evaluation of the oral form and was supported through mathematical applied Norton-Simon modeling, as established by Larry Norton, M.D., deputy physician-in-chief for breast cancer programs, at Memorial Sloan-Kettering Cancer Center and an author of the study.

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“The overexpression of ALDH in cancer cells may confer cancer stem cell-like activity and resistance to treatment, including chemotherapy and, in particular, ifosfamide and cyclophosphamide,” stated Dr. Kolb. “As a stabilized form of the active metabolite of ifosfamide, palifosfamide bypasses resistance mediated by ALDHs, in addition to conferring a potentially favorable toxicity profile compared to ifosfamide, which is known to generate toxic metabolites such as acrolein and chloroacetaldehyde. These results are compelling and merit further exploration in the clinic.”

The study was funded through a grant awarded to Dr. Lewis and Dr. Gorlick by the Kristen Ann Carr Fund (KACF) for the development of a novel treatment for pediatric sarcoma. The study’s objectives were to set the stage for further clinical study in pediatric sarcoma and other childhood cancers. Formed in 1993 in honor of Kristen Ann Carr (1971-1993), the KACF provides funding for the research and treatment sarcoma as well as the education of young physicians through the Kristen Ann Carr Fellowship at the Memorial Sloan-Kettering Cancer Center. Dr. Lewis was the first Kristen Ann Carr Fund Fellow (1993-1995), an honor awarded to him while at Memorial Sloan-Kettering.

Dr. Gorlick commented: “Sarcoma is a disease of high mortality which affects proportionately far more children than adults. It is, therefore, a critical goal of pediatric oncology research to find safer, more effective treatment options for this population. An oral drug could be a breakthrough in pediatric oncology treatment. These early, yet promising, results show the potential of palifosfamide to address this unmet medical need.”

#### **About the Kristen Ann Carr Fund**

The Kristen Ann Carr Fund ([www.kristenanncarrfund.org](http://www.kristenanncarrfund.org)) was formed in 1993, after the death of Kristen Carr, a 21-year-old who was just about to graduate from New York University. It has raised multiple millions for research into this group of rare and deadly tumors, which represent about 15% of all types of cancer in children and about one percent of all types in adults. Kristen Ann Carr Fund projects at Memorial Sloan Kettering Cancer Center include fellowships in both surgery and medical oncology. The KACF also built the Kristen Ann Carr Sarcoma Laboratory, as well as funding many projects in sarcoma and the psycho-social care of teenage and young adult cancer patients throughout the U.S. and internationally.

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## **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 and is currently in a randomized, double-blinded, placebo-controlled Phase 3 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 1 study of palifosfamide in combination with standard of care for addressing small cell lung cancer; an oral form of palifosfamide continues in preclinical study.

Darinaparsin (Zinapar™ or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) currently in a solid tumor Phase 1 study with oral administration and has been developed intravenously for the treatment of relapsed peripheral T-cell lymphoma.

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 1/2 in metastatic breast cancer.

ZIOPHARM is also pursuing the development of novel DNA-based therapeutics in the field of cancer pursuant to a partnering arrangement with Intrexon Corporation. The partnership includes two existing clinical-stage product candidates, both of which are currently in Phase 1.

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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**Forward-Looking Safe Harbor Statement:**

This press release contains certain forward-looking information about ZIOPHARM Oncology 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. Words such as "expect(s)," "feel(s)," "believe(s)," "will," "may," "anticipate(s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; financial projections and estimates and their underlying assumptions; and future performance. 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 or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether Palifosfamide, Darinaparsin, Indibulin, or any of our other therapeutic products will advance further in the 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 Palifosfamide, Darinaparsin, Indibulin, and our other therapeutic products will be successfully marketed if approved; whether our DNA-based biotherapeutics discovery and development efforts will be successful; our ability to achieve the results contemplated by our collaboration agreements; the strength and enforceability of our intellectual property rights; competition from pharmaceutical and biotechnology companies; the development of and our ability to take advantage of the market for DNA-based biotherapeutics; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our periodic and interim SEC reports including but not limited to our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, and our Current Reports on Form 8-K filed from time to time 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 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.

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