# 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): June 7, 2010

# ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

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

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

**84-1475642** (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)

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).
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

### Item 8.01 Other Events.

99.1

On June 7, 2010, the Company issued a press release announcing the presentation of updated interim data from the Company's palifosfamide study. The presentation was made by Dr. Claire Verschraegen of the University of New Mexico, Albuquerque, first author on the abstract for the Company's palifosfamide study entitled "A phase II randomized controlled trial of palifosfamide plus doxorubicin vs. doxorubicin in patients with soft tissue sarcoma (PICASSO)", in an oral session at the American Society of Clinical Oncology (ASCO) Annual Meeting on Monday, June 7, 2010.

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

Press Release, dated June 7, 2010

Item 9.01	Financial Statements and Exhibits.					
(d)	Exhibits					
	Exhibit No.	Description				

## **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 7, 2010

# **INDEX OF EXHIBITS**

Exhibit No.	Description			
99.1	Press Release, dated June 7, 2010			



# ZIOPHARM Oncology, Inc.

## ZIOPHARM Presents Positive Palifosfamide PICASSO Phase II Results in Oral Session at ASCO

-- Randomized Phase III Expected to Commence Mid-Year --

New York, NY – June 7, 2010 - ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today that Dr. Claire Verschraegen of the University of New Mexico, Albuquerque and first author of the abstract, "A phase II randomized controlled trial of palifosfamide plus doxorubicin vs. doxorubicin in patients with soft tissue sarcoma (PICASSO)," (Abstract #10004) presented in an oral session today updated positive data from PICASSO. The presentation was part of the 46<sup>th</sup> Annual American Society of Clinical Oncology (ASCO) meeting being held in Chicago, IL, from June 4<sup>th</sup> to 8<sup>th</sup>. The abstract has also been selected as part of the 2010 Best of ASCO® which features high-impact abstracts from the ASCO Annual Meeting that represent the most relevant, cuttingedge science in oncology today.

"The conclusions from the PICASSO study are that palifosfamide in combination with doxorubicin is well tolerated, easy to administer and can be given in the outpatient setting, and is active in soft tissue sarcoma," commented Dr. Verschraegen. "We look forward to the initiation of the pivotal Phase III study, which is designed based on the PICASSO study, and pending regulatory clearance by FDA through the Special Protocol Assessment process."

As previously announced, a total of 67 patients with soft tissue sarcoma (STS) were randomized with 66 treated and 62 eligible for evaluation. The study was powered to show a difference in progression free survival (PFS) between doxorubicin in combination with palifosfamide versus doxorubicin alone. The initial analysis demonstrated that the hazard ratio (HR) met the specified endpoint and after consultation with the Data Committee, independent sarcoma experts, and the Medical Advisory Board, enrollment was stopped and results were subsequently reported at the 2009 CTOS Annual Meeting. A second and subsequent analysis was conducted for an end-of-Phase-II meeting with the Food and Drug Administration (FDA) and those data were reported in the recently published ASCO abstract.

The updated study results presented to the FDA reported a hazard ratio of 0.43 favoring the palifosfamide combination with a statistically significant and clinically meaningful 3.4 month difference in median PFS. An analysis of the same data, presented today, consisting of those patients receiving either doxorubicin or doxorubicin in combination with palifosfamide for 6 cycles or less (the standard treatment period for doxorubicin) reported a hazard ratio of 0.39 (p= 0.023). This analysis also reported results for response rate -- for the palifosfamide doxorubicin combination 7 of 30 patients (23%) achieved a response, while for the doxorubicin arm alone; the response rate was 3 of 32 patients (9%). Preliminary survival data, based on a median follow-up of approximately 9 months, but with a number of patients still on study and data collection ongoing, showed a survival advantage trending in favor of the palifosfamide and doxorubicin combination over doxorubicin alone. Updated safety data showed there was similarity between the arms of the study. The most common grade 3+ events were neutropenia and elevated creatinine; both observed with similar frequency between treatment groups. There was no encephalopathy, hemorrhagic cystitis, nor Fanconi's Syndrome.

"We are very thankful to all who have contributed to the success of the PICASSO study and preparation for the initiation of the Phase III trial (PICASSO III)," added Jonathan Lewis, MD, PhD, of ZIOPHARM.

## About ZIOPHARM Oncology, Inc.:

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

Palifosfamide (Zymafos<sup>TM</sup> or ZIO-201) references a novel composition (tris formulation) that comprises the functional active metabolite of ifosfamide, a standard of care for treating sarcoma, lymphoma, testicular, and other cancers. Palifosfamide delivers only the cancer fighting component of ifosfamide. It is expected to overcome the resistance seen with ifosfamide and cyclophosphamide, two of the most commonly used DNA-alkylating drugs used to treat cancers. Palifosfamide does not have the toxic metabolites of ifosfamide that cause the debilitating side effects of "fuzzy brain" (encephalopathy) and severe bladder inflammation. It may also have other advantages. Intravenous palifosfamide is currently in a randomized Phase II trial to treat unresectable or metastatic soft tissue sarcoma in the front- and second-line setting with the Company having reported interim positive results in late 2009; a registration trial in the same setting is expected to initiate following U.S. Food and Drug Administration (FDA) review in the first half of this year. An oral form of palifosfamide has been developed preclinically to the investigational new drug application stage.

Darinaparsin (Zinapar<sup>TM</sup> or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) being developed for the treatment of various hematologic and solid cancers. Preclinical and clinical studies to date have demonstrated that darinaparsin is considerably less toxic than inorganic arsenic, particularly with regard to cardiac toxicity. The Company has reported favorable results from a Phase II trial with IV-administered darinaparsin in lymphoma, particularly peripheral T-cell lymphoma ("PTCL"), at the American Society of Clinical Oncology (ASCO) in May of 2009 which would serve as the basis for ongoing clinical study in PTCL following regulatory review and available financial resources. Phase I trials with the oral form are ongoing in both hematological malignancies and solid tumors.

Indibulin (Zybulin<sup>TM</sup> or ZIO-301) is a novel, oral tubulin binding agent that targets both mitosis and cancer cell migration. In addition, indibulin is expected to have several potential benefits, including oral dosing, application in multi-drug resistant tumors, no neuropathy and minimal overall toxicity. In multiple Phase I trials in cancer patients, oral indibulin has been administered both as a single agent and in combination with favorable activity and a promising safety profile that does not include the neurotoxicity seen with all of the other classes of tubulin binding agents. Most recently, results of oral indibulin in combination with oral capecitabine (Xeloda<sup>®</sup>) were presented at last year's American Society of Clinical Oncology (ASCO) along with the preclinical findings of a novel dosing schedule conducted under the direction of Dr. Larry Norton; employing this dosage schedule, the Company has initiated a Phase I study in breast cancer patients with the Breast Cancer Medicine Service at Memorial Sloan-Kettering Cancer Center.

ZIOPHARM's operations are located in Boston, MA with an executive office in New York City. Further information about ZIOPHARM may be found at <a href="https://www.ziopharm.com">www.ziopharm.com</a>.

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## **Forward-Looking Safe Harbor Statement:**

This press release contains forward-looking statements for ZIOPHARM Oncology, Inc. that involve risks and uncertainties that could cause the Company'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 the Company'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 the Company's product candidates, the risk that the results of clinical trials may not support the Company's claims, the risk that pre-clinical or clinical trials will proceed on schedules that are consistent with the Company's current expectations or at all, risks related to the Company'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 the Company's ability to obtain additional financing to support its operations thereafter. The Company assumes no obligation to update these forward-looking statements, except as required by law.

#### **Contacts:**

Tyler Cook ZIOPHARM Oncology, Inc. 617-259-1982 tcook@ziopharm.com

Media:
Dennis S. Dobson
(203) 258-0159
dsdobson@optonline.net