## 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): November 17, 2008

# ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation)

0-32353

84-1475642

(Commission File Number)

(IRS Employer Identification No.)

# 1180 Avenue of the Americas, 19th Floor New York, NY 10036

(Address of Principal Executive Offices) (Zip Code)

(646) 214-0700

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- o 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.

On November 17, 2008, ZIOPHARM Oncology, Inc. issued the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated November 17, 2008.

## **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.: (Registrant)

Date: November 17, 2008 By: /s/ Richard E. Bagley

Name: Richard E. Bagley

Title: President and Chief Operating Officer



# ZIOPHARM Oncology, Inc.

### ZIOPHARM ONCOLOGY PRESENTS POSITIVE DATA FROM STUDIES OF PALIFOSFAMIDE

Palifosfamide active as single agent and in combination

**LONDON, UK** - **NOVEMBER 17, 2008** - ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today that it presented positive data from a Phase I study of palifosfamide (Zymafos<sup>TM</sup>) in combination with doxorubicin at the 14<sup>th</sup> Annual Connective Tissue Oncology Society (CTOS) meeting held in London, UK, November 13 to 15. Also presented was an update of the data from the Phase II trial of palifosfamide used as a single agent in advanced sarcoma.

The Phase I trial of palifosfamide in combination with doxorubicin was fully enrolled with 13 metastatic patients, of whom 8 were still receiving therapy. The combination was well tolerated with no dose-limiting toxicities reported during a total of 51 cycles of treatment. Of 12 evaluable patients, 3 had partial responses. Of the 8 patients with soft tissue sarcoma (STS), 2 had partial responses and the remaining 6 patients were progression free with a median duration of follow-up of 15 weeks and were still on therapy.

The update from the Phase II trial investigating palifosfamide as a single agent against advanced STS revealed 3-month progression free rates of 45% overall and 55% in ifosfamide-naïve patients. The 6-month progression free rate was 23% at 6 months. These data show that palifosfamide is highly active in STS.

In both studies, none of the 19 patients who have been treated with the novel palifosfamide-T (TRIS/mannitol drug product) experienced renal toxicity nor bladder toxicity or encephalopathy commonly associated with ifosfamide treatment.

As a result of the data generated in these studies, the Company has initiated a Phase II randomized controlled trial comparing palifosfamide plus doxorubicin vs. doxorubicin in the front- and second-line treatment setting of STS.

"The study results for palifosfamide are highly encouraging," commented Sant P. Chawla, MD, Director, Sarcoma Oncology Center and a lead investigator for the studies. "The data indicate palifosfamide is active both as a single agent and in combination and bode very well for the randomized Phase II trial."

To view the presentation please visit: <a href="http://www.ziopharm.com/docs/ZIOPHARM">http://www.ziopharm.com/docs/ZIOPHARM</a> CTOS NOV 2008.pdf

#### 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) is a novel molecule that is the functional active metabolite of ifosfamide, a standard of care for treating sarcoma, testicular and other cancers. Palifosfamide delivers only the cancer fighting component of ifosfamide. It is expected to overcome the resistance of ifosfamide and cyclophosphamide in certain cancers. It does not have the toxic metabolites of ifosfamide that cause the debilitating side effects of "fuzzy brain" (encephalopathy) and severe bladder inflammation. Intravenous (IV) palifosfamide is currently in a Phase II randomized trial to treat soft tissue sarcoma. An oral form of palifosfamide has been developed preclinically and is expected to enter clinical study in 2009.

Indibulin (Zybulin<sup>TM</sup> or ZIO-301) is a novel, oral tubulin binding agent that targets both mitosis and cancer cell migration. Indibulin is expected to have several potential benefits, including oral dosing, application in multi-drug resistant tumors, no neuropathy and minimal overall toxicity. Indibulin has shown early activity in Phase I study as a single agent in many types of solid tumors. Indibulin is also currently in the Phase I portion of Phase I/II trials in combination with Tarceva® and Xeloda®. Preclinical study continues with both dose density and metronomic administration.

Darinaparsin (Zinapar<sup>TM</sup> or ZIO-101) is a novel organic arsenic being developed for the treatment of various hematologic and solid cancers. Preclinical and Phase I and II results to date demonstrate that darinaparsin is much less toxic than other forms of arsenic. Intravenous darinaparsin continues to be studied in a Phase II hematology trial with favorable treatment activity in certain lymphomas and in Phase I study with oral administration. Darinaparsin has been well tolerated in all trials to date.

ZIOPHARM's operations are located in Boston, MA with an executive office in New York. 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, and risks related to the Company's ability to protect its intellectual property and its reliance on third parties to develop its product candidates. The Company assumes no obligation to update these forward-looking statements, except as required by law.

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