

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): October 15, 2008

**ZIOPHARM Oncology, Inc.**

(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction of Incorporation)

0-32353  
(Commission File Number)

84-1475642  
(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:

- 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 15, 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 October 15, 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: October 15, 2008

By: /s/ Richard E. Bagley  
Name: Richard E. Bagley  
Title: President and Chief Operating Officer

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**ZIOPHARM Oncology, Inc.**

**ZIOPHARM Receives Positive Opinion from EMEA for Orphan Medicinal Product Designation for Palifosfamide (ZIO-201) in the Treatment of Soft Tissue Sarcoma**

NEW YORK - October 15, 2008 - ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), announced today that the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion regarding ZIOPHARM's application for orphan medicinal product designation for palifosfamide in the treatment of soft tissue sarcoma (STS).

In the European Union (EU), products targeted to treat life-threatening or very serious conditions that affect fewer than five in 10,000 people are eligible for orphan medicinal product designation. Such status provides significant advantages and assistance in obtaining final approval to market palifosfamide in the EU. These include: Ten year market exclusivity in the EU once the product is approved; direct assistance from the EMA in preparing the final protocol for drug approval; access to EMA centralized filing procedures for approval in the EU; and, reduced fees for EMA filings.

"There is a significant unmet need for additional treatments to address soft tissue sarcoma beyond locally effective surgery," said Jonathan Lewis, MD, PhD, and Chief Executive and Medical Officer of ZIOPHARM. "We are pleased to so soon have orphan drug status in Europe to augment the Orphan Drug Designation received in the United States earlier this year as we initiate patient treatment in our Phase II randomized controlled trial in STS."

**About Palifosfamide:**

Palifosfamide (IPM), the active moiety of ifosfamide (IFOS), is a bi-functional alkylator that causes irreparable inter-strand DNA cross-linking, resulting in cell death. Palifosfamide is equal to or more active than IFOS in diverse cancer models. Unlike IFOS, which is a pro-drug, palifosfamide is directly active against cancer cells. Also, unlike IFOS, palifosfamide is not metabolized to acrolein or chloroacetaldehyde which cause bladder or central nervous system toxicities. Intravenously (IV) administered palifosfamide is completing a Phase II trial in advanced soft tissue and bone sarcomas and a Phase I combination study with the FDA approved front-line therapy doxorubicin (Adriamycin®). The Company has recently initiated treatment in a randomized controlled Phase II trial of doxorubicin and doxorubicin plus palifosfamide in the front- and second-line setting of soft tissue sarcoma.

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**About European Medicines Agency:**

The EMEA is a decentralized body of the European Union with headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. Further information about EMEA may be found at [www.emea.europa.eu](http://www.emea.europa.eu).

**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 the development of three clinical programs for multiple indications. Palifosfamide (ZIO-201) is a novel molecule that is the functional active metabolite of ifosfamide, a standard of care for treating sarcoma, testicular cancer and other cancers. Palifosfamide delivers only the cancer fighting component of ifosfamide. It overcomes the resistance of ifosfamide and cyclophosphamide in certain cancers. It does not have the toxic metabolites that cause the debilitating side effects of “fuzzy brain” (encephalopathy) and severe bladder inflammation. Indibulin (ZIO-301) is a novel, oral tubulin binding agent that targets both mitosis and cancer cell migration. Indibulin has several potential benefits, including oral dosing, application in multi-drug resistant tumors, no neuropathy and minimal overall toxicity. Indibulin has shown early activity in many types of solid tumors. Darinaparsin (ZIO-101) is a novel organic arsenic being developed for the treatment of various hematologic and solid cancers. Studies demonstrate that darinaparsin is less toxic and more active in treating cancer than FDA-approved inorganic arsenic. ZIOPHARM’s operations are located in Boston MA with an executive office in New York. 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 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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