## 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): May 9, 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:

- 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)
- 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 May 9, 2008, ZIOPHARM Oncology, Inc. (the "Company") 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 May 9, 2008.

### **SIGNATURE**

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: May 9, 2008 By: /s/ Richard E. Bagley

Richard E. Bagley,

President, Chief Operating Officer and Chief Financial Officer

# Exhibit Index

Exhibit No. Description

99.1 Press Release dated May 9, 2008.



# ZIOPHARM Oncology, Inc.

### ZIOPHARM Receives FDA Orphan Drug Designation for Palifosfamide (ZIO-201) in the Treatment of Soft Tissue Sarcoma

NEW YORK - May 9, 2008 - ZIOPHARM Oncology, Inc. (NASDAQ: ZIOP), announced today that the United States Food & Drug Administration (FDA) has granted Orphan Drug Designation to palifosfamide in the treatment of Soft Tissue Sarcoma (STS). The United States Orphan Drug Act of 1983 was created to provide incentives for companies to develop and market treatments for diseases or conditions affecting fewer than 200,000 people in the United States. The Orphan Drug designation provides eligibility for a seven-year period of market exclusivity in the United States after product approval, an accelerated review process, grant funding, tax benefits and an exemption from user fees.

Soft tissue sarcomas represent a rare and diverse group of tumors that are not well understood. STS tumors can occur anywhere within the body including muscle, fat, nerves, vascular tissue, and other connective tissues. STS tumors account for about 1% of all cancers in adults and 10% in children. According to Cancer Statistics and the National Cancer Institute, there are an estimated 12,000 new cases of sarcomas diagnosed in the United States (US) each year, including approximately 9,000 cases of soft tissue sarcomas (STS) and 3,000 cases of bone sarcomas. Deaths attributable to STS are estimated at 3,500 per year, while 1,200 per year are due to bone sarcomas. Although the annual new incidence of sarcoma is relatively low, the prevalence of patients with sarcomas is quite high, with a 5-year survival rate of STS of 50% to 60%.

"There is significant unmet need for additional soft tissue sarcoma treatment beyond locally effective surgery" said Jonathan Lewis, MD, PhD, and Chief Executive Officer of ZIOPHARM. "Palifosfamide has demonstrated activity against sarcomas in heavily pre-treated patients as well as evidencing fewer side effects than similar treatments used in this setting. We are pleased to have received Orphan Drug designation and look forward to continuing to work closely with the FDA in advancing palifosfamide toward commercialization."

#### **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 currently completing phase II testing in both advanced soft tissue and bone sarcomas, while a recently initiated phase I combination study with the FDA approved front-line therapy Adriamycin® (doxorubicin) is ongoing. The final results from these studies will form the basis for an expected phase II randomized trial in the front- or second-line setting to initiate late in the third quarter of this year. Following further preclinical study, an oral form of palifosfamide is expected to enter phase I study in solid tumors early in 2009.

## About ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology, Inc. is a biopharmaceutical company engaged in the development and commercialization of a diverse, risk-sensitive portfolio of inlicensed cancer drugs to address unmet medical needs. The Company applies new insights from molecular and cancer biology to understand the efficacy and safety limitations of approved and developmental cancer therapies and identifies proprietary and related molecules for better patient treatment. For more information, visit www.ziopharm.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 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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