# **UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

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)).

	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): March 1, 2011	
	ZIOPHARM Oncology, Inc. (Exact Name of Registrant as Specified in Charter)	
<b>Delaware</b> (State or Other Jurisdiction of Incorporation)	<b>001-33038</b> (Commission File Number)	<b>84-1475672</b> (IRS Employer Identification No.)
	of the Americas	
	<sup>1</sup> Floor York, NY	10036
	pal Executive Offices)	(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 provisions:	-K is intended to simultaneously satisfy the filing obligation of the	e registrant under any of the following
☐ Written communications pursuant to Ru	le 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).	

# Item 2.02 Results of Operations and Financial Condition

On March 1, 2011, ZIOPHARM Oncology, Inc. (the "Company") issued a press release announcing its financial condition and results of operations for the fourth quarter and full year ended December 31, 2010. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The press release is furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that Section, nor shall such document be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

Item 9.01	Financial Sta	atements and Exhibits
(d)	Exhibits	
	Exhibit No.	Description
	99.1	Press Release of the Company dated March 1, 2011
		2

# **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.

Date: March 1, 2011

By: /s/ Richard Bagley

Name: Richard Bagley Title: President, Chief Operating Officer and

Chief Financial Officer

# INDEX OF EXHIBITS

Exhibit No.		Description
99.1	Press Release of the Company dated March 1, 2011	
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## **ZIOPHARM Reports Fourth Quarter and Full Year 2010 Financial Results**

**NEW YORK, NY (March 1, 2011)** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), announced today its financial results for the fourth quarter and full year 2010, and the filing of its Annual Report on Form 10-K with the Securities and Exchange Commission. Summary financials for the fourth quarter and for the year are attached.

For the fourth quarter of 2010, the Company reported net loss of \$11.9 million, or \$(0.25) per share, compared to a net income of \$1.0 million, or \$0.03 per share, in the fourth quarter of 2009. Excluding recognition of a non-cash gain of \$5.0 million attributable to the change in liability-classified warrants, there was a net loss of \$4.0 million, or \$(0.14) per share, for the fourth quarter ended December 31, 2009. Net loss for the year was \$32.7 million, or \$(0.71) per share, compared to a net loss of \$7.6 million, or \$(0.33) per share, for the full year 2009. Total operating expenses for the year were \$24.5 million, compared to \$12.1 million for 2009, or an increase of \$12.4 million. The increase in operating expenses is attributable to initiation of the Phase III palifosfamide pivotal trial during 2010 as well as related support activity. The difference between 2010 full year operating expenses and net loss is primarily attributable to a non-cash charge of \$8.9 million related to the change in fair value of liability-classified warrants. The Company ended the December 2010 quarter with cash of approximately \$60.4 million which, along with net proceeds of approximately \$71 million from financing transactions completed in January and February 2011, and under current assumptions which are subject to change, is expected to support operations into late 2012.

"ZIOPHARM achieved a number of significant milestones in 2010 with regard to our clinical and financial goals, including the launch of PICASSO 3, our pivotal, Phase III study of palifosfamide in metastatic soft-tissue sarcoma," stated Jonathan Lewis, MD, PhD, Chief Executive Officer and Chief Medical Officer of ZIOPHARM. "With the addition in early 2011 of Intrexon's products and revolutionary platform technologies to our research and development efforts, ZIOPHARM is well positioned to deliver a range of important cancer medicines to areas of unmet medical need. As always, we will continue pursuing this important goal while operating under rigorous financial discipline."

## Full Year 2010 and Recent Highlights

#### Palifosfamide:

- · In January, ZIOPHARM announced that it received a Notice of Allowance from the U.S. Patent and Trademark Office for claims covering the Company's proprietary palifosfamide (ZIO-201 or Zymafos<sup>TM</sup>) composition.
- In June, the Company announced that updated positive data from its Phase II PICASSO study, a randomized controlled trial of palifosfamide plus doxorubicin versus doxorubicin in patients with soft tissue sarcoma, were presented in an oral session at the 46th Annual American Society of Clinical Oncology (ASCO) Meeting. The abstract was selected as part of the 2010 Best of ASCO®, which features high-impact abstracts from the ASCO Annual Meeting that represent the most relevant, cutting-edge science in oncology today.

The presented data demonstrated that palifosfamide in combination with doxorubicin is well tolerated, easy to administer, can be given in the outpatient setting, and is active in soft tissue sarcoma. Further, the study reported a hazard ratio of 0.39 (p= 0.023) for patients receiving either doxorubicin or doxorubicin in combination with palifosfamide for 6 cycles or less (the standard treatment period for doxorubicin). Updated safety data showed there was similarity between the arms of the study. The most common grade 3+ events were neutropenia and elevated creatinine. There was no encephalopathy, hemorrhagic cystitis or Fanconi's Syndrome.

- In July, the Company announced the initiation of the PICASSO 3 trial, an international, randomized, double-blinded, placebo-controlled Phase III trial of palifosfamide (Zymafos<sup>TM</sup> or ZIO-201) in patients with front-line metastatic soft-tissue sarcoma. The study is designed to enroll approximately 424 patients worldwide. PICASSO 3 is designed to evaluate the safety and efficacy of palifosfamide administered with doxorubicin compared with doxorubicin administered with placebo, with no crossover between arms. Progression-free survival (PFS) is the primary endpoint for accelerated approval, with overall survival (OS) as the primary endpoint for full approval.
- · In December, the Company announced the initiation of a Phase I, single arm, dose escalation study at the Indiana University Cancer Center of intravenous palifosfamide (ZIO-201) in combination with etoposide (VP-16) and cisplatin/carboplatin (platinum) in the treatment of small cell lung cancer (SCLC) and other cancers. The study, conducted under the direction of Lawrence Einhorn, M.D., Lance Armstrong Professor of Oncology, will assess the safety of the palifosfamide/etoposide/platinum regimen for a planned randomized Phase II study in SCLC patients with extensive disease where the etoposide/platinum combination is standard of care.

# Darinaparsin:

- · In April, ZIOPHARM announced that preclinical data on darinaparsin (Zinapar™, or ZIO-101) were presented at the American Association for Cancer Research (AACR) Annual Meeting. The studies, presented by a Vanderbilt University Medical Center team, looked at the ability of darinaparsin (organic arsenic) to induce RNA stress granules, a critical survival adaptation mechanism for cells. The findings demonstrated that darinaparsin has a different spectrum of activity than sodium arsenite and can elicit differential molecular mechanisms of cell killing on specific classes of tumor cells.
- In September, the Company announced that darinaparsin was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) in the treatment of peripheral T-cell Lymphoma (PTCL). Darinaparsin has demonstrated favorable results in a Phase II trial in lymphoma, particularly PTCL. The Company began enrolling patients in Phase I study of darinaparsin in combination with CHOP (Cyclophosphamide, Doxorubicin, Vincristin, and Prednisone), the current standard of care for front-line PTCL, in the fourth quarter to confirm the tolerability of the combination. Subject to the outcome of this study and further dialogue with the FDA, the Company expects to move forward likely with a two-stage potentially pivotal trial in the relapsed setting of PTCL in late 2011. An oral form is in a Phase I trial in solid tumors.
- · Also in September, the Company announced that it was granted Patent No. 4,571,408 by the Japanese Patent Office with claims covering pharmaceutical compositions, including oral formulations, or various organic arsenic compounds, including darinaparsin, and the use of these compositions and the organic arsenic compounds for the treatment of cancer, including as part of a combination therapy.
- · In November, the Company announced that important new preclinical data on the efficacy of darinaparsin in various solid tumor models were presented at the EORTC-NCI-AACR International Symposium on Molecular Targets and Cancer Therapeutics. The preclinical work was designed to study darinaparsin's cytotoxic and radiosensitizing effects against different solid tumor cell lines under both normoxic (NO) and hypoxic (HO) conditions. The findings demonstrated that darinaparsin's cytotoxic and radiation enhancing modes of action are distinct from other cytotoxic agents and were not dependent on generation of reactive oxygen species and DNA damage under HO.

- · In December, the Company announced that new preclinical data on the novel mechanism of darinaparsin in various lymphoma models were presented at the 52nd Annual Meeting and Exposition of the American Society of Hematology (ASH). The preclinical work was designed to study the effects of increasing concentrations of darinaparsin in T Cell Lymphoma and resistant Hodgkin's Lymphoma. The data demonstrated darinaparsin's potent and targeted effects on two signaling pathways important to proliferation in hematologic malignancies, AKT and MEK/ERK, an effect which can be enhanced in combination with MEK/ERK-targeted inhibitors.
- · In January 2011, the Company announced that The Committee for Orphan Medicinal Products (COMP) within the European Medicines Agency (EMA) adopted a positive opinion for darinaparsin designation as an orphan medicinal product for the treatment of PTCL. A positive opinion by the COMP immediately precedes official designation of darinaparsin as an orphan drug by the European Commission (EC).

## Indibulin:

· In April, ZIOPHARM initiated a Phase I/II study of indibulin (Zybulin™ or ZIO-101) in metastatic breast cancer, a study which is being conducted at Memorial Sloan-Kettering Cancer Center. The study employs a novel, mathematically-determined administration schedule for indibulin that was developed by Larry Norton, M.D., Deputy Physician-in-Chief for Breast Cancer Programs at Memorial Sloan-Kettering and Medical Director of the Evelyn H. Lauder Breast Center.

## Synthetic Biology:

· In January, 2011, the Company announced a global, exclusive channel partnership in oncology with Intrexon Corporation, a next-generation synthetic biology company. Under the partnership, ZIOPHARM has rights to Intrexon's entire human in vivo effector platform within the field of oncology (including two lead clinical-stage product candidates) which the Company will use to develop and commercialize DNA-based therapeutics. As part of the overall exclusive channel partnership arrangement, ZIOPHARM also welcomed Intrexon's Chairman and CEO, RJ Kirk, to its Board of Directors.

## Financing Highlights:

- · In May, ZIOPHARM announced that it had raised approximately \$32.8 million, after deducting underwriting discounts and commissions and other estimated offering expenses, in a public offering of its common stock.
- · In November, the Company announced that it has been awarded \$733 thousand in funding under the U.S. Government's Qualifying Therapeutic Discovery Project (QTDP) program for three of its lead product candidates: palifosfamide, darinaparsin and indibulin.
- · In January 2011, in conjunction with entry into the Intrexon exclusive channel partnership, Intrexon purchased \$11.6 million worth of ZIOPHARM common stock in a private placement. Subject to certain conditions and limitations, Intrexon further committed to purchase up to \$50.0 million in conjunction with future qualifying Company securities offerings. Intrexon's \$11.0 million participation in the Company's February 2011 public offering was applied against this aggregate purchase commitment.
- · In February 2011, the Company announced that it had raised approximately \$59.4 million, after deducting underwriting discounts and commissions and estimated offering expenses, in a public offering of its common stock.

## 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<sup>TM</sup> or ZIO-201) is a novel DNA cross-linker in class with bendamustine, ifosfamide, and cyclophosphamide. ZIOPHARM is currently enrolling patients in a randomized, double-blinded, placebo-controlled Phase III 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 I intravenous study of palifosfamide in combination with the standard of care addressing small cell lung cancer and an oral form of the drug for treatment of solid tumors is currently in the advanced preclinical stage of development.

Darinaparsin (Zinapar $^{TM}$  or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) being developed intravenously for the treatment of peripheral T-cell lymphoma with a pivotal study expected to begin in late 2011. An oral form is in a Phase I trial in solid tumors.

Indibulin (Zybulin<sup>TM</sup> or ZIO-301) is a novel, oral tubulin binding agent that that is expected to have several benefits including oral dosing, application in multi-drug resistant tumors, no neuropathy and minimal overall toxicity. It is currently being studied in Phase I/II in metastatic breast cancer.

ZIOPHARM is also pursuing the development of novel DNA-based biotherapeutics in the field of cancer pursuant to a partnering arrangement with Intrexon Corporation. The partnership includes two existing clinical-stage product candidates, the first of which is in a Phase Ib study and the second of which is the basis of an Investigational New Drug application that ZIOPHARM expects to submit during the first half of 2011.

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 ZIOPHARM Oncology'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 ZIOPHARM Oncology'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 ZIOPHARM Oncology's product candidates, the risk that the results of clinical trials may not support ZIOPHARM Oncology's claims, the risk that pre-clinical or clinical trials may not proceed on schedules that are consistent with ZIOPHARM Oncology's current expectations or at all, risks related to ZIOPHARM Oncology'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 ZIOPHARM Oncology's ability to obtain additional financing to support its operations thereafter, as well as other risks regarding ZIOPHARM Oncology's that are discussed under the heading "Risk Factors" in ZIOPHARM Oncology's filings with the United States Securities and Exchange Commission. Forward-looking statements can be identified by the use of words such as "may," "will," "intend," "should," "could," "can," "would," "expect," "believe," "estimate," "predict," "potential," "plan," "is designed to," "target" and similar expressions. ZIOPHARM Oncology assumes no obligation to updat

# ZIOPHARM Oncology, Inc. Condensed Statements of Operations (in thousands except share and per share data)

	Three Months Ended December 31, (unaudited)			Year Ended December 31, (unaudited)				
		2010	_	2009		2010	_	2009
Revenue	\$	-	\$	<u>-</u>	\$	<u>-</u>	\$	_
Operating expenses:								
Research and development		3,038		1,216		12,910		4,556
General and administrative		3,323		2,813		11,636		7,567
Total operating expenses	_	6,361		4,029		24,546	Ξ	12,123
Loss from operations		(6,361)		(4,029)		(24,546)		(12,123)
Other income (expense), net		736		12		765		13
Change in fair value of warrants		(6,226)		4,981		(8,889)		4,461
Net income (loss)	\$	(11,851)	\$	964	\$	(32,670)	\$	(7,649)
Basic and diluted net income (loss) per share	\$	(0.25)	\$	0.03	\$	(0.71)	\$	(0.33)
Weighted average common shares outstanding used to compute basic net income (loss) per share	_	48,040,198	_	28,002,429	_	46,003,996	_	23,108,039
Weighted average common shares outstanding used to compute diluted net income (loss) per share	_	48,040,198	_	30,012,082	_	46,003,996	_	23,108,039

# ZIOPHARM Oncology, Inc. Balance Sheet Data (in thousands)

	December 31, 2010 (unaudited)	December 31, 2009 (unaudited)
Cash and cash equivalents	60,392	48,839
Working capital	57,204	46,098
Total assets	61,520	49,736
Total stockholders' equity	30,553	28,104

## **Contacts:**

## For ZIOPHARM:

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