

**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 13, 2011**

ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-33038

(Commission File Number)

84-1475672

(IRS Employer
Identification No.)

1180 Avenue of the Americas

19th 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).
 - 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

From November 13, 2011 through November 15, 2011, the Company issued three press releases announcing results presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place November 12-16 in San Francisco.

The first press release announced the results from preclinical studies of darinaparsin (Zinapar[®] or ZIO-101), a novel organic arsenic, in prostate cancer were presented at the Conference.

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

The second press release announced promising clinical results from an ongoing multicenter Phase 1b, open-label, dose escalation study of intravenous palifosfamide (Zymafos[®] or ZIO-201) in combination with etoposide and carboplatin in patients with small cell lung cancer and other selected cancers.

A copy of the above referenced press release is filed as Exhibit 99.2 to this Current Report of Form 8-K.

The third press release announced new preclinical data from two separate studies of darinaparsin (Zinapar[®] or ZIO-101), a novel organic arsenic, in various solid tumor models at the Conference.

A copy of the above referenced press release is filed as Exhibit 99.3 to this Current Report of Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated November 13, 2011
99.2	Press Release of the Company dated November 14, 2011
99.3	Press Release of the Company dated November 15, 2011

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/ Caesar Belbel

Name: Caesar Belbel

Title: Executive Vice President, Chief Legal Officer and Secretary

Date: November 15, 2011

INDEX OF EXHIBITS

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ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology Presents Preclinical Data for Darinaparsin Effect on Hedgehog Signaling Pathway in Prostate Cancer at AACR-NCI-EORTC Meeting

NEW YORK, NY – November 13, 2011 – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a drug development company employing small molecule and synthetic biology approaches to cancer therapy, announced today that results from preclinical studies of darinaparsin (Zinapar[®] or ZIO-101), a novel organic arsenic, in prostate cancer were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place November 12-16 in San Francisco. In addition to Company authors, the studies included authors Joseph R. Bertino M.D. and Nitu Bansal Ph.D. from UMDNJ-The Cancer Institute of New Jersey.

The studies were designed to evaluate the effect of darinaparsin on the Hedgehog signaling pathway in prostate cancer. Aberrant hedgehog signaling has been implicated in a number of cancers due to its association with the transformation of adult stem cells into cancer stem cells. Data from the studies demonstrate that darinaparsin is a potent inhibitor of DU145 prostate cells, which inhibited prostate spheroid growth (IC₅₀:2uM) and prostate stem cell colony formation. Western analysis showed that darinaparsin decreased levels of the transcription factor Gli2, a downstream effector of the activated Hedgehog pathway which is elevated in certain cancers. Further, combination studies with taxotere, a U.S. Food and Drug Administration-approved drug for the treatment of patients with advanced prostate cancer, showed synergistic cell destruction at high fixed doses of the drugs.

“We know from past research that arsenic trioxide inhibits growth in certain tumors through its activity against the Hedgehog pathway,” commented Joseph Bertino, M.D., Associate Director and Chief Scientific Officer of the Cancer Institute of New Jersey, University Professor of Medicine and Pharmacology at UMDNJ-Robert Wood Johnson, former President of AACR and ASCO, and a member of ZIOPHARM's Medical Advisory Board. “Due to inorganic arsenic trioxide's severe cardiotoxicity and neurotoxicity profile, darinaparsin, an organic arsenic, was thought to be a far better treatment candidate and these studies encourage additional preclinical and clinical study, as a single agent and in combination.”

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's small molecule programs include:

Palifosfamide (Zymafos® or ZIO-201) is a novel DNA cross-linker in class with bendamustine, ifosfamide, and cyclophosphamide and is currently in a randomized, double-blinded, placebo-controlled Phase 3 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 1 study of palifosfamide in combination with standard of care for addressing small cell lung cancer; an oral form of palifosfamide continues in preclinical study.

Darinaparsin (Zinapar® or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) currently in a solid tumor Phase 1 study with oral administration and has been developed intravenously for the treatment of relapsed peripheral T-cell lymphoma.

Indibulin (Zybulin™ or ZIO-301) is a novel, oral tubulin binding agent that is expected to have several potential benefits including oral dosing, application in multi-drug resistant tumors, no neuropathy and a quite tolerable toxicity profile. It is currently being studied in Phase 1/2 in metastatic breast cancer.

ZIOPHARM is also pursuing the development of novel DNA-based therapeutics in the field of cancer pursuant to a partnering arrangement with Intrexon Corporation. The partnership includes two existing clinical-stage product candidates, both of which are currently in Phase 1.

ZIOPHARM's principal operations are located in Boston, MA with an executive office in New York City and a small satellite office in Germantown, MD. Further information about ZIOPHARM may be found at www.ziopharm.com.

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Forward-Looking Safe Harbor Statement:

This press release contains certain forward-looking information about ZIOPHARM Oncology that is intended to be covered by the safe harbor for "forward-looking statements" provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. Words such as "expect(s)," "feel(s)," "believe(s)," "will," "may," "anticipate(s)" and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; financial projections and estimates and their underlying assumptions; and future performance. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include, but are not limited to: whether Palifosfamide, Darinaparsin, Indibulin, or any of our other therapeutic products will advance further in the clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether Palifosfamide, Darinaparsin, Indibulin, and our other therapeutic products will be successfully marketed if approved; whether our DNA-based biotherapeutics discovery and development efforts will be successful; our ability to achieve the results contemplated by our collaboration agreements; the strength and enforceability of our intellectual property rights; competition from pharmaceutical and biotechnology companies; the development of and our ability to take advantage of the market for DNA-based biotherapeutics; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our periodic and interim SEC reports including but not limited to our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, our Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, and our Current Reports on Form 8-K filed from time to time with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

Contacts:**For ZIOPHARM:**

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

Media:

David Pitts
Argot Partners
212-600-1902
david@argotpartners.com



ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology Announces Promising Data from Phase 1b Study of Palifosfamide in Small Cell Lung and Other Cancers at AACR-NCI-EORTC Meeting

NEW YORK, NY – November 14, 2011 – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a drug development company employing small molecule and synthetic biology approaches to cancer therapy, announced today promising clinical results from an ongoing multicenter Phase 1b, open-label, dose escalation study of intravenous (IV) palifosfamide (Zymafos[®] or ZIO-201) in combination with etoposide and carboplatin in patients with small cell lung cancer (SCLC) and other selected cancers. The data are being presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, being held November 12-16, in San Francisco.

Palifosfamide is a novel DNA cross-linker in class with bendamustine, ifosfamide, and cyclophosphamide. The ongoing Phase 1b study was designed to assess the safety and efficacy of palifosfamide in combination with carboplatin and etoposide (PaCE) in SCLC and other cancers in which carboplatin plus etoposide is considered an appropriate therapeutic option. A previous randomized study evaluating the addition of ifosfamide to cisplatin and etoposide in SCLC demonstrated improved survival, but with a disabling increase in toxicity with the combination. The rationale for substituting palifosfamide for ifosfamide in this three-drug regimen includes the abrogation of ifosfamide-metabolite related toxicities, an ability to increase the dose delivered over time, and avoiding resistance mediated by aldehyde dehydrogenase (ALDH) overexpression. ALDH overexpression is associated with cancer cell stem-like potential in several tumor types and is thought to confer resistance to ifosfamide and cyclophosphamide.

A total of 22 patients (11 females and 11 males) have been treated to date in the study: 7 with SCLC, 3 with non-SCLC, 3 with ovarian cancer, 1 with germ cell tumor and 8 with other cancers. The maximum tolerated dose of palifosfamide was determined to be 130 mg/m² when administered in combination with etoposide (90 mg/m² with an additional cohort ongoing at 100 mg/m²) and carboplatin (AUC4). The dose limiting toxicity was neutropenic fever.

Of the 22 patients, 13 are evaluable for efficacy. Seven are not yet evaluable for response and 2 patients did not continue beyond cycle 1 due to an adverse event. Among the 13 patients evaluable for efficacy, there were 5 patients with partial responses (PR), 4 with stable disease (SD), and 4 with progressive disease (PD). Of the 4 patients with SCLC, 2 showed PR, 1 SD and 1 PD. Partial responses were also seen in non-SCLC (1), ovarian cancer (1), and germ cell tumor (1).

“I am very enthusiastic about this investigational drug in SCLC. Ifosfamide, in combination with carboplatin and etoposide, is one of the few treatments to have demonstrated a survival advantage in SCLC, yet is often too toxic to be used effectively,” said Wael A. Harb, M.D., Medical Director of Clinical Research, Indiana University Health Arnett, Hoosier Oncology Group, and lead author. “The combination with palifosfamide appears to be well tolerated and has demonstrated promising clinical activity in SCLC, germ cell tumor and ovarian cancer. I look forward to participating in the confirmatory study in SCLC.”

“Based on past studies and my experience in SCLC, I am encouraged by these data and the potential of a combination regimen using palifosfamide, carboplatin and etoposide,” said Lawrence Einhorn, M.D., Distinguished Professor at the Simon Cancer Center of Indiana University Medical Center, Lance Armstrong Foundation Chair in Oncology, former President of ASCO and a member of ZIOPHARM’s Medical Advisory Board. “Small cell lung cancer is a disease in desperate need of an effective treatment option, as the standard of care has remained unchanged after decades of research. These early data are not only an important step forward for palifosfamide in SCLC but also potentially other solid tumors.”

SCLC is almost exclusively associated with cigarette smoking and the majority of patients with extensive disease are treated front-line but relapse with a very high mortality within one year. According to the American Cancer Society, approximately 15 percent of lung cancers are SCLC, or an incidence of approximately 33,400 patients yearly in the U.S. There is expected to be a substantially growing incidence worldwide.

About ZIOPHARM Oncology, Inc.:

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Darinaparsin (Zinapar® or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) currently in a solid tumor Phase 1 study with oral administration and has been developed intravenously for the treatment of relapsed peripheral T-cell lymphoma.

Indibulin (Zybulin™ or ZIO-301) is a novel, oral tubulin binding agent that is expected to have several potential benefits including oral dosing, application in multi-drug resistant tumors, no neuropathy and a quite tolerable toxicity profile. It is currently being studied in Phase 1/2 in metastatic breast cancer.

ZIOPHARM is also pursuing the development of novel DNA-based therapeutics in the field of cancer pursuant to a partnering arrangement with Intrexon Corporation. The partnership includes two existing clinical-stage product candidates, both of which are currently in Phase 1.

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ZIOPHARM Oncology, Inc.

ZIOPHARM Oncology Presents New Darinaparsin Preclinical Prostate and Pancreatic Cancer Data at AACR-NCI-EORTC Meeting

NEW YORK, NY – November 15, 2011 – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a drug development company employing small molecule and synthetic biology approaches to cancer therapy, announced today new preclinical data from two separate studies of darinaparsin (Zinapar[®] or ZIO-101), a novel organic arsenic, in various solid tumor models at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place November 12-16 in San Francisco. Both studies were conducted at the Stanford University School of Medicine by lead author, Junqiang Tian, M.D., Ph.D., senior author, Susan J. Knox, M.D., Ph.D., from the Department of Radiation Oncology, and were performed in collaboration with co-author, Donna Peehl, Ph.D., Professor of Urology.

In the first study, titled “Darinaparsin sensitizes solid tumors but not normal tissues to radiation,” human prostatic [hormone-independent (HI) LAPC-4] and pancreatic [PANC-1] tumor models were treated with darinaparsin (100 mg/kg) or saline (control), with the addition of local tumor x-ray irradiation. Previous preclinical work at Stanford established darinaparsin’s cytotoxic and radiation enhancing modes of action under both normoxic (NO) and hypoxic (HO) conditions in prostate cancer, pancreatic cancer, cervical cancer, and glioblastoma cell lines. Hypoxia is an important condition in the microenvironment of solid tumor cells which creates resistance to cytotoxic drugs and radiation and causes cancer stem cells to re-grow the tumor. This study was performed to assess the effect of different radiation dosing regimens as well as the potential radiosensitizing effect of darinaparsin on normal radiosensitive intestine and bone marrow.

Intestinal crypt microcolony assay and blood cell counts were used to assess the effect of darinaparsin on intestinal and bone marrow cell radiosensitivity, respectively. In both the prostate and pancreatic tumor models, a single dose of darinaparsin four hours before radiation significantly enhanced radiation-induced tumor growth inhibition, with a significant delay of tumor volume doubling time observed from 8.4 days with radiation alone and 6.2 days with darinaparsin alone, to 14.7 days for the combined treatment of radiation and darinaparsin. Darinaparsin-mediated radiosensitization was observed in prostate tumors with both single and fractionated irradiation dosing regimens. Importantly, no systemic toxicity was observed with the darinaparsin treatment alone, and darinaparsin did not sensitize normal intestinal epithelium and bone marrow to the effect of radiation at the studied dose.

“These results suggest that darinaparsin has the potential to sensitize relatively radioresistant tumors without affecting normal tissues,” commented senior author, Susan J. Knox. “They further suggest that darinaparsin may increase the therapeutic index of radiation therapy and, as was shown with our first study, have near-term translational potential.”

A second study, titled “Darinaparsin is an anti-solid tumor cytotoxin *in vivo*,” again evaluated prostate and pancreatic tumor models treated with darinaparsin (100 mg/kg) or saline (control). In both the prostate and pancreatic tumor models, darinaparsin significantly inhibited tumor growth ($p < 0.0001$), with the average tumor volume doubling time increasing from 3.95 days to 11.8 days in the prostate tumor model, and 3.83 days to 6.82 days in the pancreatic tumor model. Importantly, no significant systemic toxicities were exhibited at studied dose, as assessed by organ histology and blood biochemistry.

Dr. Knox remarked: “Darinaparsin was found to have significant cytotoxic activity in these two well-established solid tumor models, without apparent systemic toxicity. With darinaparsin currently in clinical development, these findings may have near-term translational potential.”

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