# 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): **August 1, 2011**

# ZIOPHARM Oncology, Inc.

(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **001-33038** | **84-1475672** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **1180 Avenue of the Americas**<br>**19th Floor**<br>**New York, NY** | **10036** |
|---|---|
| (Address of Principal 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)

[Missing Graphic Reference]

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:

- 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 2.02** **Results of Operations and Financial Condition**

On August 1, 2011, ZIOPHARM Oncology, Inc. (the "Company") issued a press release announcing its financial condition and results of operations for the second quarter of 2011. 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 Statements and Exhibits**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of the Company dated August 1, 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/ Richard Bagley

Date: August 1, 2011

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 August 1, 2011 |

**Exhibit 99.1**

# ZIOPHARM Oncology, Inc.

## ZIOPHARM Reports Second Quarter Financial Results and Highlights

***Ends quarter with $130 million in cash and cash equivalents***

**NEW YORK, NY – August 1, 2011** - ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a drug development company employing small molecule and synthetic biology approaches to cancer therapy, today reported its financial results for the three months ended June 30, 2011, and provided an update on the Company's activities in the second quarter.

For the second quarter of 2011, the Company's cash used in operations was $5.8 million, an increase of $1.5 million from $4.3 million for the same period of 2010. The increase in spending is attributable primarily to research and development activities for the "PICASSO 3" Phase 3 trial of palifosfamide in metastatic soft tissue sarcoma, as well as DNA-based therapeutics. The Company ended the June 2011 quarter with cash of approximately $130.3 million. The Company expects its existing cash resources to support operations into early 2013; however, this expectation is subject to change based on the scope and progress of the Company's research and development programs.

The net loss for the second quarter of 2011 was $10.7 million, or $(0.16) per share, compared to net income of $9.0 million, or $0.21 per share for the second quarter of 2010. The increase in net loss of $19.7 million was primarily attributable to a non-cash gain of $14.1 million from the change in liability classified warrants realized by the Company in the second quarter of 2010. Increased clinical trial expenses also contributed to the increase in net loss. The Company expects its clinical trial expenses to continue increasing as the pivotal palifosfamide trial further enrolls and as additional trials for palifosfamide, darinaparsin, indibulin and DNA-based therapeutics are initiated or expanded.

**Second Quarter and Recent Highlights**

- **Presented Positive Data from First-Ever Treatment (ZIN-CTI-001) Demonstrating Small Molecule-Controlled Production of Anticancer Protein in Humans.** At the 2011 Annual Meeting of the American Society of Clinical Oncology (ASCO) in June, Douglas J. Schwartzentruber, MD, FACS, of the Indiana University Health Goshen Center for Cancer Care, presented clinical results from the first-ever treatment demonstrating control by an orally-administered small molecule over the transgene-encoded expression of a therapeutic anti-cancer protein in humans. Results from the Phase 1b study evaluating ZIN-CTI-001, the Company's most advanced synthetic biology product candidate, in 10 patients with advanced melanoma demonstrated that the candidate is well-tolerated (primarily mild to moderate adverse events including nausea, vomiting, anorexia, arthralgia, fever or chills and one significant adverse event (SAE) that completely resolved), with a substantial disease control rate of 50% among evaluable patients (n=8). The data also showed a correlation between T-cell immune responses and clinical outcome, a desired outcome with the highly focused use of Interleukin-12 (IL-12), a potent anticancer cytokine. The maximum tolerated dose (MTD) has not yet been reached in the study.

- **Announced FDA Acceptance of IND Application for Second Synthetic Biology Product Candidate, ZIN ATI-001.** In June, the U.S. Food & Drug Administration (FDA) accepted the Company's May 2011 investigational new drug (IND) application to begin clinical study of ZIN ATI-001, a novel DNA-based therapeutic candidate. The Phase 1 study has been initiated and will evaluate safety in addition to immunological and biological effects of the therapeutic candidate in patients with melanoma. Through intratumoral injection, ZIN ATI-001 employs an adenoviral vector (Ad) to deliver a gene that expresses IL-12 directly into the patient's tumor cells.

- **Presented Preclinical Study Results from Controlled In Vivo Expression of Genes with Broad and Potent Antitumor Activity.** ZIOPHARM and Intrexon presented results from two preclinical studies examining the tightly controlled, intra-tumoral expression of IL-12 in, murine models of melanoma, colon, lung, leukemia, breast and pancreatic cancers at the 2011 Annual Meeting of the American Society of Gene and Cell Therapy (ASGCT) in June.

- **Appointed Hagop Youssoufian, M.Sc., M.D., Chief Medical Officer.** In July, the Company appointed Hagop Youssoufian, M.Sc., M.D., Executive Vice President and Chief Medical Officer. In this position, Dr. Youssoufian will be responsible for the Company's clinical product strategies.

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™ 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 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 intravenous study of palifosfamide in combination with 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™ or ZIO-101) is a novel mitochondrial-targeted agent (organic arsenic) being developed intravenously for the treatment of relapsed peripheral T-cell lymphoma likely with a two-stage potentially pivotal study. An oral form is in a Phase 1 trial in solid tumors.

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 operations are located in Boston, MA and Germantown, MD with an executive office in New York City. Further information about ZIOPHARM may be found at 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 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 that 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 will 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 more fully 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 update these forward-looking statements, except as required by law.

| ZIOPHARM Oncology, Inc.<br>Condensed Statements of Operations<br>(in thousands except share and per share data) | | |
|---|---|---|
| | Three Months Ended June 30, (unaudited) | |
| | 2011 | 2010 |
| Research contract revenue | $ 200 | $ - |
| Operating expenses: | | |
| Research and development, including costs of research contracts | 9,125 | 2,222 |
| General and administrative | 3,923 | 2,894 |
| Total operating expenses | 13,048 | 5,116 |
| Loss from operations | (12,848) | (5,116) |
| Other income (expense), net | 9 | 13 |
| Change in fair value of warrants | 2,115 | 14,142 |
| Net income (loss) | $ (10,724) | $ 9,039 |
| Net income (loss) per share - basic | $ (0.16) | $ 0.21 |
| Net income (loss) per share - diluted | $ (0.16) | $ 0.19 |
| Weighted average common shares outstanding used to compute net income (loss) per share - basic | 67,229,098 | 42,364,791 |
| Weighted average common shares outstanding used to compute net income (loss) per share - diluted | 67,229,098 | 48,822,686 |

| ZIOPHARM Oncology, Inc. | | |
|---|---|---|
| Balance Sheet Data | | |
| (in thousands) | | |
| | | |
| | **June 30, 2011 (unaudited)** | **December 31, 2010 (unaudited)** |
| | | |
| Cash and cash equivalents | 130,282 | 60,392 |
| Working capital | 122,607 | 57,204 |
| Total assets | 132,821 | 61,520 |
| Total stockholders' equity | 84,128 | 30,553 |

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