

**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 3, 2012**

**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**  
**20<sup>th</sup> 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**

On May 3, 2012, ZIOPHARM Oncology, Inc. issued a press release announcing its financial condition and results of operations for the three months ended March 31, 2012. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01**      **Financial Statements and Exhibits**

(d)      Exhibits

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Press Release of ZIOPHARM Oncology, Inc. dated May 3, 2012

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: May 3, 2012

By: /s/ Richard Bagley

Name: Richard Bagley

Title: President, Chief Operating Officer and Chief Financial Officer

**INDEX OF EXHIBITS**

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99.1	Press Release of ZIOPHARM Oncology, Inc. dated May 3, 2012



## ZIOPHARM Oncology, Inc.

### ZIOPHARM Reports First Quarter Financial Results

**NEW YORK, NY – May 3, 2012** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today its financial results for the first quarter ended March 31, 2012, and provided an update on the Company's activities.

The Company's cash used in operations during the first quarter was \$25.9 million, an increase of \$17.7 million from \$8.2 million for the same period of 2011. Included in the cash used in operations was a one-time, non-recurring pre-payment of \$10.0 million related to our DNA therapeutics (synthetic biology) research and development program. The increase in spending of \$7.7 million is attributable to research and development activities for the palifosfamide pivotal Phase 3 trial (PICASSO 3) in front-line metastatic soft tissue sarcoma (STS), start-up activities for the Phase 3 trial in small cell lung cancer (SCLC) expected to initiate early in the third quarter of 2012, and additional activities supporting palifosfamide development. Excluding recognition of a non-cash loss of \$5.8 million attributable to the change in liability-classified warrants, there was a net loss of \$18.7 million, or \$(0.25) per share, for the first quarter ended March 31, 2012. In comparison, the net loss for the first quarter of 2011 was \$10.4 million, or \$(0.17) per share, excluding recognition of a non-cash loss of \$11.1 million attributable to the change in liability-classified warrants and a one-time, non-cash charge of \$17.5 million for in-process research and development expenses. When including recognition of non-cash losses, the Company reported a net loss of \$24.5 million for the first quarter of 2012, or \$(0.32) per share, compared to a net loss of \$39.0 million, or \$(0.65) per share, in the first quarter of 2011.

The Company ended the March 2012 quarter with cash and cash equivalents of approximately \$128.0 million. The Company expects its existing cash resources to support operations into the second half of 2013.

#### Substantial Progress and Milestones with Lead Programs

##### Palifosfamide (ZIO-201):

During the first quarter of 2012, significant progress was made in the palifosfamide programs. STS advancements included nearly completed enrollment of the Company's pivotal PICASSO 3 trial, a third review and recommendation to continue by the PICASSO 3 Independent Data Monitoring Committee, and positive preliminary overall survival data from the Company's Phase 2 PICASSO study, supporting the PICASSO 3 study's design. Beyond STS, start-up activities accelerated for the SCLC trial, with expectations now to initiate the study early in the third quarter of 2012. Additionally, ZIOPHARM presented two preclinical studies demonstrating compelling results for palifosfamide in breast cancer at the 2012 American Association for Cancer Research (AACR) Annual Meeting. Based on results from these studies, ZIOPHARM plans to explore the use of palifosfamide as a single agent and/or in combination with IL-12 DNA in additional clinical studies. ZIOPHARM also announced that the U.S. Food and Drug Administration has accepted its investigational new drug application for the oral capsule form of palifosfamide, with a clinical study plan under evaluation, offering several potential patient-oriented advantages and an outpatient treatment for expanded global commercial reach.

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“Sarcoma patients, for the first time in decades, will benefit from a new wave of therapeutic options,” said Jonathan Lewis, M.D., Ph.D., Chief Executive Officer of ZIOPHARM. “Palifosfamide, with results of the PICASSO 3 study expected in the second half of 2012, is well positioned to potentially be the first front-line treatment in over 30 years. With its favorable safety profile and activity against key pathways of drug resistance, palifosfamide has also begun to demonstrate its versatility with single agent or combination activity in small cell lung and metastatic breast cancers, two areas of significant unmet need. Pivotal studies in these indications are planned or under evaluation, making this a very exciting time for our lead program.”

#### **DNA Therapeutics (Synthetic Biology):**

ZIOPHARM presented preclinical data at the 2012 AACR Annual Meeting demonstrating the significant anti-tumor activity of interleukin-12 (IL-12) and interferon alpha, two proteins involved in immune response to cancers, expressed in vivo utilizing a regulated gene system. The study assessed anti-tumor activity in lung and breast cancer mouse models utilizing intratumoral administration of adenovirus-delivered DNA therapeutics equipped with a novel biologic switch (RheoSwitch Therapeutic System<sup>®</sup>) to regulate expression of murine IL-12 or murine IFN $\alpha$ . In both tumor models, significant tumor growth inhibition was observed. The presentation was recognized as among the best science by the AACR Program Committee, a designation awarded to the top few presentations. Additionally, ongoing Phase 1 studies continue for Ad-IL-12 and DC-IL-12.

#### **About ZIOPHARM Oncology, Inc.:**

ZIOPHARM Oncology is a biopharmaceutical company engaged in the development and commercialization of small molecule and synthetic biology approaches to new cancer therapies. The Company's clinical programs include:

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Palifosfamide (ZIO-201), a novel DNA-targeted cancer treatment that bypasses drug resistance mediated by ALDH (aldehyde dehydrogenase), an enzyme associated with cancer stem cells, and has a favorable toxicity profile. Intravenous palifosfamide is currently being studied in a randomized, double-blinded, placebo-controlled Phase 3 trial (PICASSO 3) for the treatment of front-line metastatic soft tissue sarcoma. The initiation of a pivotal Phase 3 trial in front-line metastatic small cell lung cancer is also expected early in the third quarter of 2012. Additionally, the Company is developing an oral capsule form of palifosfamide.

IL-12 DNA, a novel DNA therapeutic that is delivered to the patient's tumor and expresses interleukin-12, a protein that controls anti-cancer immune responses. IL-12 DNA is currently in two Phase 1 studies, with plans to move into Phase 2 studies. ZIOPHARM's DNA therapeutics are being developed in partnership with Intrexon Corporation through a revolutionary synthetic biology platform that allows for targeted, controlled production of therapies in humans with a biologic on/off switch (the RheoSwitch Therapeutic System<sup>®</sup>). Preclinical and discovery work with multiple therapeutic approaches, such as antibodies, immunotoxins, and protein decoys, is expected to result in multiple clinical candidates in the next 12 to 24 months.

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

Darinaparsin (ZIO-101) is a novel mitochondrial- and hedgehog-targeted agent (organic arsenic) currently in ongoing studies with Solasia Pharma K.K.

ZIOPHARM's operations are located in Boston, MA; Germantown, MD; and New York City. Further information about ZIOPHARM may be found at [www.ziopharm.com](http://www.ziopharm.com).

#### **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 filed from time to time with the Securities and Exchange Commission, including but not limited to our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, and our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2012. 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.

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<u>2012</u>	<u>2011</u>
Revenue	\$ 200	\$ 67
Operating expenses:		
Research and development	13,985	24,641
General and administrative	4,848	3,352
Total operating expenses	<u>18,833</u>	<u>27,993</u>
Loss from operations	(18,633)	(27,926)
Other income, net	(26)	(2)
Change in fair value of warrants	(5,811)	(11,080)
Net loss	<u>\$ (24,470)</u>	<u>\$ (39,008)</u>
Basic and diluted net loss per share	<u>\$ (0.32)</u>	<u>\$ (0.65)</u>
Weighted average common shares outstanding used to compute basic and diluted net loss per share	<u>75,620,130</u>	<u>60,412,689</u>

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

	<u>March 31,</u>	<u>December 31,</u>
	<u>2012</u>	<u>2011</u>
Cash and cash equivalents	128,008	104,713
Working capital	124,481	92,742
Total assets	140,873	108,108
Total stockholders' equity	97,700	71,607



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