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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 26, 2013**

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**ZIOPHARM Oncology, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**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)

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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 March 26, 2013, ZIOPHARM Oncology, Inc., or the Company, issued a press release announcing that its Phase 3 trial of palifosfamide (ZIO-201) in first-line metastatic soft tissue sarcoma, entitled PICASSO 3, did not meet its primary endpoint of progression-free survival. With this outcome, the Company has made the decision to immediately terminate development of palifosfamide in first-line metastatic soft tissue sarcoma and place exclusive strategic focus on its synthetic biology programs, which are being developed in partnership with Intrexon Corporation. A copy of the above referenced press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

At 8:30 a.m. Eastern Time on March 26, 2013, the Company will hold a conference call to discuss the PICASSO 3 trial.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of the Company dated March 26, 2013

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 J. Belbel

Name: Caesar J. Belbel

Title: Executive Vice President and Chief Legal Officer

Date: March 26, 2013

**INDEX OF EXHIBITS**

**Exhibit  
No.**

**Description**

99.1 Press release of the Company dated March 26, 2013



## **ZIOPHARM Oncology, Inc.**

### **ZIOPHARM Terminates Development of Palifosfamide in Metastatic Soft Tissue Sarcoma**

#### ***Restructuring to Place Exclusive Strategic Focus on Synthetic Biology Programs***

#### ***Company to Host Conference Call Today, March 26, 2013 at 8:30 AM ET***

**NEW YORK, NY – March, 26, 2013** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, announced today that its Phase 3 trial of palifosfamide (ZIO-201) for the treatment of metastatic soft tissue sarcoma in the first-line setting (PICASSO 3) did not meet its primary endpoint of progression-free survival (PFS). The study's independent data monitoring committee (IDMC) has recommended that patients be followed for overall survival (OS), the study's secondary endpoint, however the Company does not expect to continue follow up for OS. Palifosfamide was well tolerated, with a safety profile in combination with doxorubicin observed in the study comparable with other palifosfamide clinical trials in soft tissue sarcoma. Full data from PICASSO 3 will be submitted for publication in a scientific journal.

With this outcome, ZIOPHARM has made the decision to immediately place exclusive strategic focus on its synthetic biology programs, which are being developed in partnership with Intrexon Corporation. The lead therapeutic candidate in this program is Ad-RTS IL-12, a DNA therapeutic to enable controlled delivery of therapeutic interleukin-12 (IL-12), a protein important for an immune response to cancer. This is achieved by placing IL-12 under the control of Intrexon's proprietary biological "switch" (the RheoSwitch Therapeutic System<sup>®</sup>, RTS<sup>®</sup>) to turn on/off the therapeutic protein expression. Ad-RTS IL-12 is currently being tested in two Phase 2 studies, the first for the treatment of advanced melanoma, and the second in combination with palifosfamide for the treatment of non-resectable recurrent or metastatic breast cancer.

A highly focused team within the Company will be deployed in support of these programs. As a result, a restructuring plan is immediately being put into place to align staffing to current objectives and to marshal its resources toward achieving success with its synthetic biology programs.

"We are disappointed that the PICASSO 3 study did not meet its primary endpoint of progression-free survival," said Jonathan Lewis, M.D., Ph.D., Chief Executive Officer of ZIOPHARM. "We sincerely thank the trial investigators, clinical sites and the ZIOPHARM team for conducting a highly rigorous study, and are deeply appreciative to the cancer patients and their families for their participation in this trial."

Dr. Lewis added: "It is imperative that the Company rapidly focus its resources and efforts on our highly promising synthetic biology programs, employing therapeutic motifs that represent the next-generation in biotechnology."

## **Conference Call and Webcast March 26, 2013, at 8:30 AM ET**

ZIOPHARM will host a conference call and live audio webcast today, March 26, 2013, at 8:30 AM ET to discuss the PICASSO 3 trial. The call can be accessed by dialing (877) 303-9850 (U.S. and Canada) or (408) 427-3732 (international). The passcode for the conference call is 'ZIOPHARM.' To access the live audio webcast, or the subsequent archived recording, visit the "Investors - Events & Presentations" section of the ZIOPHARM website at [www.ziopharm.com](http://www.ziopharm.com). The webcast will be recorded and available for replay on the Company's website for two (2) weeks.

### **About PICASSO 3**

The PICASSO 3 trial is an international, randomized, double-blinded, placebo-controlled study. A total of 447 patients with metastatic soft tissue sarcoma were randomized to receive either intravenous palifosfamide plus doxorubicin (150 mg/m<sup>2</sup> 3 days every 21 days for a maximum of 6 cycles followed by 75 mg/m<sup>2</sup> 1 day every 21 days for a maximum of 6 cycles) or doxorubicin alone (75 mg/m<sup>2</sup> 1 day every 21 days for a maximum of 6 cycles). The primary endpoint for the study is improvement in PFS, with overall survival as a key secondary endpoint. Other secondary endpoints include quality of life assessments, and the safety and tolerability of this combination in this patient population. PICASSO 3 was conducted at more than 150 clinical centers in North America, Europe, South America, Australia, Israel and Asia.

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

ZIOPHARM Oncology is a biopharmaceutical company focused on the development and commercialization of new cancer therapies. The Company's clinical programs include:

Ad-RTS IL-12 is currently being tested in two Phase 2 studies, the first for the treatment of advanced melanoma, and the second in combination with palifosfamide for the treatment of non-resectable recurrent or metastatic breast cancer. Ad-RTS IL-12 uses synthetic biology to enable controlled delivery of therapeutic interleukin-12 (IL-12), a protein important for an immune response to cancer. ZIOPHARM's DNA synthetic biology platform is being developed in partnership with Intrexon Corporation and employs an inducible gene-delivery system that enables controlled delivery of genes that produce therapeutic proteins to treat cancer. This is achieved by placing IL-12 under the control of Intrexon's proprietary biological "switch" (the RheoSwitch Therapeutic System<sup>®</sup>, RTS<sup>®</sup>) to turn on/off the therapeutic protein expression at the tumor site.

Palifosfamide (ZIO-201) is a potent, bi-functional DNA alkylating agent that has activity in multiple tumors by evading typical resistance pathways. Palifosfamide is in the same class as bendamustine, cyclophosphamide, and ifosfamide.

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, 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, Ad-RTS IL-12, 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, Ad-RTS IL-12, Darinaparsin, Indibulin, and our other therapeutic products will be successfully marketed if approved; whether any of our other therapeutic product 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 our therapeutic products; 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, 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.

**Contact:**

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