# 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 7, 2013

# **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.)

One First Avenue, Parris Building 34, Navy Yard Plaza Boston, Massachusetts (Address of Principal Executive Offices)

02129 (Zip Code)

(Address of Principal Executive Offices)

(617) 259-1970

(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)).

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).

## Item 8.01 Other Events

On May 7, 2013, ZIOPHARM Oncology, Inc. issued a press release announcing its financial condition and results of operations for the three months ended March 31, 2013. 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
  - Exhibit<br/>No.Description99.1Press Release of ZIOPHARM Oncology, Inc. dated May 7, 2013

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.

By: /s/ Jason A. Amello

Name: Jason A. Amello

Title: Executive Vice President, Chief Financial Officer and Treasurer

Date: May 7, 2013

# INDEX OF EXHIBITS

# Exhibit <u>Description</u>

99.1 Press Release of ZIOPHARM Oncology, Inc. dated May 7, 2013

4





# **ZIOPHARM Oncology, Inc.**

#### ZIOPHARM Announces First Quarter Financial Results and Key Developments

#### Highlights Include Initiation of Phase 2 Study of Ad-RTS-IL-12 in Advanced Breast Cancer

**BOSTON, MA – May 7, 2013 –** ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today announced financial results for the first quarter ended March 31, 2013, and provided an update on the Company's key developments.

ZIOPHARM reported a GAAP net loss of \$12.8 million for the first quarter of 2013, or \$(0.15) per share, compared to a GAAP net loss of \$24.5 million, or \$(0.32) per share, in the first quarter of 2012. Excluding non-cash income of \$10.8 million attributable to the change in liability-classified warrants, Non-GAAP<sup>1</sup> net loss was \$23.6 million, or \$(0.28) per share, for the quarter ended March 31, 2013. In comparison, Non-GAAP<sup>1</sup> net loss for the first quarter of 2012 was \$18.7 million, or \$(0.25) per share, which excludes a non-cash loss of \$5.8 million attributable to the change in liability-classified warrants.

Operating expenses for the first quarter of 2013 were \$23.8 million compared to \$18.8 million for the first quarter of 2012. The \$5.0 million increase is attributable to ongoing activities for the adaptive Phase 3 trial (MATISSE) in small cell lung cancer (SCLC) that was initiated during the second quarter of 2012 and to expanded development and manufacturing activities supporting the Company's palifosfamide and synthetic biology program.

The Company's cash used in operations during the first quarter of 2013 was \$18.2 million, a decrease of \$7.7 million from \$25.9 million for the same period of 2012. The Company ended the first quarter with cash and cash equivalents of approximately \$55.7 million and expects its existing cash resources to support operations into the first quarter of 2014.

#### **Recent Corporate Highlights**

In March, ZIOPHARM announced the initiation of a randomized, open label Phase 2 clinical study of Ad-RTS-IL-12 in combination with palifosfamide to treat patients with non-resectable recurrent or metastatic breast cancer. Ad-RTS-IL-12, a DNA-based therapeutic designed to express interleukin-12 (IL-12), a protein important to the generation of an immune response to cancer, is the Company's lead drug candidate. The two-part, multi-center U.S. study will enroll up to 68 patients with non-resectable, recurrent or metastatic breast cancer who have visible lesions or lesions accessible by injection. The study is designed to assess the safety and efficacy of the therapeutic combination of Ad-RTS-IL-12 and a chemotherapy agent.

Several other synthetic biology approaches have been designed, tested and built in our discovery and preclinical programs, including significant progress made with multi-genic approaches to cancer treatment.

In April, the Company announced the presentation of results from a study in a breast cancer murine preclinical model demonstrating the anti-tumor effects and tolerability of Ad-RTS-mIL-12. The data were presented at the American Association for Cancer Research 2013 Annual Meeting. The study was conducted jointly by ZIOPHARM and Intrexon Corporation.

In April, the Company completed a workforce reduction to lower operating costs as part of its program to terminate development of palifosfamide in first-line metastatic soft tissue sarcoma and place strategic focus on its synthetic biology platforms, which the Company is developing in partnership with Intrexon Corporation.

# 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 enhancing the development of an immune response to cancer. In partnership with Intrexon Corporation, ZIOPHARM's DNA synthetic biology platform employs an inducible gene-delivery system that enables controlled delivery of genes that produce therapeutic proteins to treat cancer. This controlled delivery is achieved by producing IL-12 under the control of Intrexon's proprietary biological "switch" (the RheoSwitch Therapeutic System® or RTS® platform) 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. It is currently being studied in an adaptive Phase 3 study in small cell lung cancer. Enrollment in this study was suspended with 188 subjects randomized, and being followed for overall survival. Data is expected in the first half of 2014. 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. Further information about ZIOPHARM may be found at www.ziopharm.com.

#### Forward-Looking Safe Harbor Statement:

This press release contains certain forward-looking information about ZIOPHARM Oncology, Inc. that is intended to be covered by the safe harbor for "forwardlooking 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 other 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, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013. 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.

<sup>&</sup>lt;sup>1</sup> Non-GAAP net loss is calculated as GAAP net loss less the expense (or plus the income) associated with the change in fair value of the liability-classified warrants. Non-GAAP net loss per share is calculated by dividing the Non-GAAP net loss by the weighted average common shares outstanding.

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

	Three Months Ended March 31,			
	2013		2012	
Revenue	\$	200	\$	200
Operating expenses:				
Research and development		19,112		13,985
General and administrative		4,671		4,848
Total operating expenses		23,783		18,833
Loss from operations		(23,583)		(18,633)
Other income (expense), net		(4)		(26)
Change in fair value of warrants		10,788		(5,811)
Net loss	\$	(12,799)	\$	(24,470)
Basic and diluted net loss per share	\$	(0.15)	\$	(0.32)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	82	,906,080	7	5,620,130

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

	March 31, 2013	December 31, 2012
Cash and cash equivalents	\$55,655	\$ 73,306
Working capital	40,199	61,412
Total assets	63,346	83,404
Total stockholders' equity	37,893	48,445

# Contact:

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## Media Contacts:

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