# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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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 3, 2014

# 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)

 $\tag{617) 259-1970}$  (Registrant's telephone number, including area code)

Not applicable (Former Name or Former Address, if Changed Since Last Report)

ck 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 risions:
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)).

#### Item 2.02 Results of Operations and Financial Condition

On March 3, 2014, ZIOPHARM Oncology, Inc. issued a press release announcing its financial condition and results of operations for the three months and year ended December 31, 2013. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

This information, including the information contained in the press release furnished as Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any of the Company's filings, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

### Item 9.01 <u>Financial Statements and Exhibits</u>

(d) Exhibits

Exhibit No.

Description

99.1 Press Release of ZIOPHARM Oncology, Inc. dated March 3, 2014

### **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.

Date: March 3, 2014

ZIOPHARM Oncology, Inc.

By: /s/ Kevin G. Lafond

Name: Kevin G. Lafond

Title: Vice President Finance, Chief Accounting Officer and Treasurer

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# **INDEX OF EXHIBITS**

Exhibit No. Description

99.1 Press Release of ZIOPHARM Oncology, Inc. dated March 3, 2014

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#### ZIOPHARM Reports Fourth-Quarter and Full-Year 2013 Financial Results and Reviews Recent Activities

**BOSTON, MA – March 3, 2014 –** ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today announced financial results for the fourth quarter and full year ended December 31, 2013 and provided an update on the company's product development activities.

"Working with our partner Intrexon Corporation, we made extensive progress in 2013 toward expanding, and demonstrating the transformative potential of, what is a game-changing technology platform," said Jonathan Lewis, M.D., Ph.D., chief executive officer of ZIOPHARM. "This progress will continue in 2014, where we expect to achieve clinical milestones with lead candidate Ad-RTS-IL-12, continue to advance several, cutting edge new product candidates to the clinic, and potentially secure key partnerships."

#### **Corporate Highlights**

ZIOPHARM is advancing a number of clinical- and preclinical-stage, gene based therapies and related technologies to allow precise regulation of protein expression and control of cellular function. Controlled expression and delivery of DNA and therapeutic proteins is achieved through Intrexon Corporation's (NYSE: XON) RheoSwitch Therapeutic System® (RTS®) technology, the most advanced clinical method for precisely modulating protein production in gene based therapies.

ZIOPHARM recently presented results, including at the 2013 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, demonstrating the use of both monogenic and multigenic systems and therapies in various cancer models, targeting cancer cell signaling pathways and the stimulation of immune response to cancer. These data also highlighted the potential for gene delivery via multiple platforms, including viral vectors, mesenchymal stem cells and embedded cellular bioreactors.

For Ad-RTS-IL-12, a Phase 2, novel gene expression platform for the immune system cytokine interleukin-12, ZIOPHARM and its academic collaborators have presented clinical and preclinical results demonstrating:

- The tight control of IL-12 mRNA expression using the oral activator ligand veledimex, and a corresponding increase in biologic activity, as demonstrated by an increase in tumor infiltrating lymphocytes in the tumor microenvironment;
- On-mechanism and on-target response and toxicity, as demonstrated by potent biologic activity in injected and non-injected lesions in patients with advanced melanoma, as well as an adverse event profile consistent with immunotherapy use and immune response;
- The ability to optimize dose and scheduling to refine response and tolerability, as enabled by a rapid reversal of adverse events after veledimex dosing is stopped.

ZIOPHARM is currently conducting or planning Phase 2 studies of Ad-RTS-IL-12, alone or in combination with existing treatment standards, in melanoma and breast cancer, with plans to initiate a Phase 1 study in high-grade gliomas (brain cancer). The Company also expects to file several investigational new drug (IND) applications for novel, multigenic gene therapies through 2015.

#### Fourth-Quarter 2013 Financial Results

- Net loss for the fourth quarter of 2013 was \$8.9 million, or \$(0.09) per share, compared to a net loss of \$30.2 million, or \$(0.37) per share, for the fourth quarter of 2012. Included in the loss for the fourth quarter of 2013 was a non-cash expense of \$1.8 million compared to a non-cash gain of \$8.6 million for the fourth quarter of 2012. The non-cash expense is related to the change in the fair value of the company's outstanding liability-classified warrants.
- Research and development expenses were \$2.7 million for the fourth quarter of 2013 compared to \$35.0 million for the fourth quarter of 2012. The decrease of \$32.3 million in research and development expenses is primarily attributable to reduced development of our small molecule drugs and a reduction in employees resulting from the company's restructuring put into effect during the second quarter of 2013.
- General and administrative expenses were \$4.2 million for the fourth quarter of 2013 compared to \$4.1 million for the fourth quarter of 2012.

#### **Full Year 2013 Financial Results**

• Net loss for the year ended December 31, 2013 was \$57.1 million, or \$(0.66) per share, compared to a net loss of \$96.1 million, or \$(1.22) per share, for the year ended December 31, 2012. Included in the loss for the year ended December 31, 2013 was a non-cash gain of \$1.2 million compared to a non-cash gain of \$6.1 million for the year ended December 31, 2012. The non-cash expense is related to the change in the fair value of the company's outstanding liability-classified warrants.

- Research and development expenses were \$42.9 million for the year ended December 31, 2013 compared to \$83.4 million for the year ended December 31, 2012. The decrease of \$40.5 million in research and development expenses is primarily attributable to reduced development of our small-molecule drugs and a reduction in employees resulting from the company's restructuring during the second quarter of 2013.
- General and administrative expenses were \$15.7 million for the year ended December 31, 2013 compared to \$19.5 million for the year ended December 31, 2012. The decrease of \$3.8 million in general and administrative expenses is primarily related to a reduction in employees resulting from the company's restructuring.
- The company ended the year with cash and cash equivalents of approximately \$68.2 million and expects its existing cash resources to support operations into the second quarter of 2015.

#### About ZIOPHARM Oncology, Inc.:

ZIOPHARM Oncology is a Boston, Massachusetts-based biotechnology company employing novel gene expression and control technology to deliver DNA for the treatment of cancer. ZIOPHARM's technology platform employs Intrexon Corporation's RheoSwitch Therapeutic System® technology to turn on and off, and precisely modulate, gene expression at the cancer site in order to improve the therapeutic index. This technology is currently being evaluated in Phase 2 clinical studies of the immune system cytokine interleukin-12 for the treatment of breast cancer and advanced melanoma. Multiple new Investigational New Drug applications for new targets using synthetic biology technology are expected through 2015. ZIOPHARM is also developing novel small molecules as potential cancer therapeutics.

#### 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 "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 Ad-RTS-IL-12,

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 Ad-RTS-IL-12, palifosfamide, 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, 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.

#### **Trademarks**

RheoSwitch Therapeutic System® (RTS®) technology is a registered trademark of Intrexon Corporation.

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

	Three Months Ended December 31,				Year Ended December 31,			
		2013		2012		2013	_	2012
Revenue	\$	200	\$	200	\$	800	\$	800
Operating expenses:								
Research and development		2,718		34,982		42,852		83,446
General and administrative		4,201		4,062		15,661		19,523
Total operating expenses		6,919		39,044		58,513		102,969
Loss from operations		(6,719)		(38,844)		(57,713)		(102,169)
Other income (expense), net		(391)		53		(579)		(13)
Change in fair value of warrants		(1,793)		8,566		1,185		6,050
Net loss	\$	(8,903)	\$	(30,225)	\$	(57,107)	\$	(96,132)
Basic and diluted net loss per share	\$	(0.09)	\$	(0.37)	\$	(0.66)	\$	(1.22)
Weighted average common shares outstanding used to compute basic and diluted net loss per share	94	,524,944	81	1,347,231	85	5,943,175	7	8,546,112

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

	December 31, 	December 31, 2012
Cash and cash equivalents	68,204	73,306
Working capital	62,506	61,412
Total assets	71,754	83,404
Total stockholders' equity	49,383	48,445

#### **Contact:**

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