# 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): November 8, 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:

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 8.01 Other Events

On November 8, 2012, ZIOPHARM Oncology, Inc. issued a press release announcing its financial condition and results of operations for the nine months ended September 30, 2012. A copy of the press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 <u>Financial Stateme</u>		ments and Exhibits
(d)	Exhibits	
	Exhibit No.	Description
	99.1	Press Release of ZIOPHARM Oncology, Inc. dated November 8, 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: November 8, 2012

By: /s/ Jason A. Amello

Name: Jason A. Amello Title: Executive Vice President and Chief Financial Officer

# **INDEX OF EXHIBITS**

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# **ZIOPHARM** Oncology, Inc.

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

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

**NEW YORK, NY – November 8, 2012** – ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) today announced financial results for the third quarter ended September 30, 2012, and provided an update on the Company's key development activities.

The Company reported a GAAP net loss of \$17.8 million for the third quarter of 2012, or \$(0.23) per share, compared to a GAAP net loss of \$0.8 million, or \$(0.01) per share, in the third quarter of 2011. Excluding non-cash income of \$3.9 million attributable to the change in liability-classified warrants, Non-GAAP<sup>1</sup> net loss was \$21.8 million, or \$(0.28) per share, for the third quarter ended September 30, 2012. In comparison, Non-GAAP<sup>1</sup> net loss for the third quarter of 2011 was \$14.2 million, or \$(0.21) per share, which excludes non-cash income of \$13.4 million attributable to the change in liability-classified warrants.

Operating expenses for the third quarter of 2012 were \$21.9 million compared to \$14.4 million for the third quarter of 2011. The \$7.5 million increase is attributable to start-up activities for the Phase 3 trial (MATISSE) in small cell lung cancer (SCLC) that was initiated during the second quarter, expanded development and manufacturing activities supporting the Company's palifosfamide and synthetic biology therapeutics program, and severance and other costs related to the termination of certain employees announced in July.

The Company's cash used in operations during the third quarter was \$14.7 million, an increase of \$3.6 million from \$11.1 million for the same period of 2011. The Company ended the third quarter with cash and cash equivalents of approximately \$95.3 million and expects its existing cash resources to support operations into the second half of 2013.

#### Palifosfamide (ZIO-201):

ZIOPHARM continues to make positive progress in its two, pivotal palifosfamide programs. PICASSO 3, the Company's international, randomized, doubleblinded, placebo-controlled Phase 3 study of palifosfamide in first-line metastatic soft tissue sarcoma completed enrollment in June 2012, with progressionfree survival data from this trial expected in the fourth quarter of 2012, subject to an update on study progress at the next meeting of the study's Independent Data Monitoring Committee, which is scheduled for mid-November 2012. The Company also continues to enroll patients in the Phase 3 MATISSE study, a multi-center, open-label, adaptive, randomized study in SCLC, being conducted at centers in North America, Europe, Australia and Asia. MATISSE includes a prospectively planned opportunity for modification of the study's sample size that is designed to maintain adequate power across a range of significant and meaningful outcomes, while keeping time and resources spent conducting the trial to a minimum.

### **Synthetic Biology:**

ZIOPHARM recently announced that compelling clinical activity was seen in its Phase 1 study of Ad-RTS IL-12, that uses synthetic biology to enable controlled, local delivery of therapeutic interleukin-12 (IL-12), in patients with advanced melanoma (Stage III or IV). The data showed clinical activity in 5 of 7 (71%) patients dosed at the two highest dose levels, as well as a correlation between T-cell immune responses and clinical outcome, with no dose-limiting toxicities. Three serious adverse events (SAE) were reported (n=3/13): two related to therapy (pyrexia and cytopenia), and one that was unrelated (deep vein thrombosis).

Based on this early activity, tolerability and determination of a biologically effective dose, the Company also announced dosing of the first patient in the Phase 2 study. The Phase 2 multi-center, single-arm, open-label expansion study will enroll up to 15 patients with unresectable Stage III or IV melanoma and further evaluate the safety and efficacy of intratumoral injections of Ad-RTS IL-12 in combination with an oral activator ligand. Data from this study are expected in the first half of 2013. In connection with the achievement of this milestone, ZIOPHARM has issued 3,636,926 shares of the Company's common stock to Intrexon Corporation in accordance with the terms of the Exclusive Channel Partner Agreement (ECP) between the companies entered into in January 2011. All of the shares issued to Intrexon will be unregistered but subject to certain registration rights in accordance with the Registration Rights Agreement entered into by the companies at the time of the ECP.

### 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:

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. Intravenous palifosfamide is currently being studied in a randomized, double-blinded, placebo-controlled Phase 3 trial (PICASSO 3) for the treatment of first-line metastatic soft tissue sarcoma and is also in a pivotal Phase 3 trial (MATISSE) for first-line metastatic small cell lung cancer. Additionally, the Company is developing an oral capsule form of palifosfamide.

Ad-RTS IL-12 is currently being tested in a Phase 2 study. Ad-RTS IL-12 uses synthetic biology to enable controlled, local 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, local 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.

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.

### 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 "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 forwardlooking 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 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 September 30, 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.

<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 September 30,		
	2012		2011	
Revenue	\$ 20	0 \$	200	
Operating expenses:				
Research and development	16,21	5	10,667	
General and administrative	5,71	2	3,742	
Total operating expenses	21,92	7	14,409	
Loss from operations	(21,72	7)	(14,209)	
Other income (expense), net	(4	2)	19	
Change in fair value of warrants	3,94	5	13,388	
Net loss	\$ (17,82	4) \$	(802)	
Basic and diluted net loss per share	\$ (0.2	3) \$	(0.01)	
Weighted average common shares outstanding used to compute basic and diluted net loss per share	78,670,22	2	68,104,934	
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### ZIOPHARM Oncology, Inc. Balance Sheet Data (in thousands) (unaudited)

	September 30, 2012	December 31, 2011
Cash and cash equivalents	95,333	104,713
Working capital	80,845	92,742
Total assets	105,640	108,108
Total stockholders' equity	59,028	71,607

## Contact:

## For ZIOPHARM

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