# 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): August 2, 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 August 2, 2012, ZIOPHARM Oncology, Inc. issued a press release announcing its financial condition and results of operations for the three and six months ended June 30, 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
  - Exhibit No. Description
    - 99.1 Press Release of ZIOPHARM Oncology, Inc. dated August 2, 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: August 2, 2012

By: /s/ Jason A. Amello

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

# **INDEX OF EXHIBITS**

Exhibit No.	Description
99.1	Press Release of ZIOPHARM Oncology, Inc. dated August 2, 2012



# **ZIOPHARM Oncology, Inc.**

#### **ZIOPHARM** Announces Second Quarter Financial Results and Key Developments

#### Highlights Include Completion of Enrollment in PICASSO 3 Trial for Soft Tissue Sarcoma and Initiation of MATISSE Study for Small Cell Lung Cancer

**NEW YORK, NY – August 2, 2012 –** ZIOPHARM Oncology, Inc. (Nasdaq: ZIOP) announced today its financial results for the second quarter ended June 30, 2012, and provided an update on the Company's development activities.

The Company's cash used in operations during the second quarter was \$16.8 million, an increase of \$11.0 million from \$5.8 million for the same period of 2011. The increase in spending is attributable to research and development activities for the palifosfamide pivotal Phase 3 trial (PICASSO 3) in first-line metastatic soft tissue sarcoma (STS) which completed enrollment during the quarter, start-up activities for the Phase 3 trial (MATISSE) in small cell lung cancer (SCLC) that was initiated during the quarter, and expanding development activities supporting the Company's palifosfamide and DNA-based therapeutics programs.

The Company reported a GAAP net loss of \$23.6 million for the second quarter of 2012, or \$(0.30) per share, compared to a GAAP net loss of \$10.7 million, or \$(0.16) per share, in the first quarter of 2011. Excluding a non-cash expense of \$0.7 million attributable to the change in liability-classified warrants, Non-GAAP<sup>1</sup> net loss was \$23.0 million, or \$(0.29) per share, for the second quarter ended June 30, 2012. In comparison, Non-GAAP<sup>1</sup>net loss for the second quarter of 2011 was \$12.8 million, or \$(0.19) per share, which excludes non-cash income of \$2.1 million attributable to the change in liability-classified warrants.

The Company ended the second quarter of 2012 with cash and cash equivalents of approximately \$110.4 million and expects its existing cash resources to support operations into the second half of 2013.

#### Palifosfamide (ZIO-201):

In the second quarter of 2012, ZIOPHARM made substantial progress in its palifosfamide programs. The Company completed enrollment in the pivotal Phase 3 trial (PICASSO 3) for metastatic first-line STS and, in June, initiated a pivotal Phase 3 multi-center, open-label, adaptive, randomized study (MATISSE) of palifosfamide for the treatment of SCLC. The MATISSE study, which is being conducted at centers in North America, Europe, Australia and Asia, includes a prospectively planned opportunity for modification of the study's sample size 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.

The Company also announced recently that, after completing a planned, pre-specified futility analysis, the Independent Data Monitoring Committee for the PICASSO 3 trial has recommended that the trial proceed as designed and conducted. By design, there is no interim efficacy analysis. Outcome in progression-free survival, the study's primary endpoint for accelerated approval, is anticipated in the fourth quarter of 2012.

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

ZIOPHARM continues to advance its DNA therapeutics platform, with special focus on its interleukin-12 (IL-12) DNA program. During the quarter, the Company hosted a research and development day where development plans for this technology and Ad IL-12, ZIOPHARM's lead synthetic biology clinical candidate, currently in a Phase 1b trial for metastatic melanoma, were outlined. Upon successful completion of this study, the Company expects to initiate a Phase 2 study of Ad IL-12 in melanoma. ZIOPHARM continues to explore the suitability of Ad IL-12 in other indications, including breast cancer and head and neck cancer, in addition to leveraging clinical evidence from this program to advance additional candidates, currently in the discovery and research stage, toward the clinic.

#### 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), 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 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.

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 1b 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 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)," "well," "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, 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 June 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>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 June 30,		
	 2012		2011
Revenue	\$ 200	\$	200
Operating expenses:			
Research and development	18,264		9,125
General and administrative	4,902		3,923
Total operating expenses	23,166		13,048
Loss from operations	(22,966)		(12,848)
Other income, net	3		9
Change in fair value of warrants	(650)		2,115
Net loss	\$ (23,613)	\$	(10,724)
Basic and diluted net loss per share	\$ (0.30)	\$	(0.16)
	 	_	<u> </u>
Weighted average common shares outstanding used			
to compute basic and diluted net loss per share	78,514,718		67,229,098
· ·	 ,	_	,==0,000

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

	June 30, 2012	December 31, 2011
Cash and cash equivalents	110,391	104,713
Working capital	101,666	92,742
Total assets	122,380	108,108
Total stockholders' equity	75,636	71,607

## Contact:

## For ZIOPHARM

Nicole Jones ZIOPHARM Oncology, Inc. 617-778-2266 njones@ziopharm.com

## Media Contacts:

David Schull or Lena Evans Russo Partners, LLC 858-717-2310 212-845-4262 david.schull@russopartnersllc.com lena.evans@russopartnersllc.com