



## ZIOPHARM Oncology, Inc.

Stock Price (9/25/08):	\$1.58
52 wk Range:	\$1.07 - \$3.65
Market Cap:	\$33.77M
Shares Out:	~21MM
Avg Vol (3 month):	25,993
Fiscal YE:	Dec. 31

ZIOPHARM Oncology is a biopharmaceutical company engaged in the development and commercialization of a diverse portfolio of cancer drugs. ZIOPHARM is currently developing three compounds in the clinic in both niche and broad-based indications, and expects its clinical programs to mature significantly over the course of 2008. The market potential for these product is estimated at over \$2 billion.

## INVESTMENT HIGHLIGHTS

**Multiple product development/registration pathways in both niche and broad-based indications.** Indibulin (ZIO-301) is presently in two separate Phase I/II studies, one in combination with Tarceva® and the other in combination with Xeloda®. Composite data for indibulin's two Phase I trials was presented in July 2008. Palifosfamide is currently in a Phase II randomized controlled trial with doxorubicin in patients with unresectable or metastatic soft-tissue sarcoma (PICASSO trial). A single agent Phase II clinical trial in sarcoma has been completed and awaiting final data, a Phase I soft-tissue sarcoma combination trial with doxorubicin (Adriamycin®) is nearing completion, and an oral study is planned. A Phase II trial of darinaparsin (ZIO-101) is nearing completion in patients with primary liver cancer and advanced myeloma, a Phase II trial is ongoing in patients with lymphomas, and a Phase I oral trial is in progress.

The Company is focused on developing oral formulations of its therapies to address the needs and convenience of patients and healthcare providers.

**Multiple data points in all programs over next 12 months lead to potential registration strategies.** Indibulin - Final composite data from three Phase I trials was achieved in July 08 → potential for initiation of an indibulin registration phase in 2009. Palifosfamide - Final Phase II sarcoma data in 2H08 → global Phase II randomized controlled trial in progress. Darinaparsin - Final Phase II myeloma and heme data, interim Phase II liver data and preliminary oral Phase I data in 2H08.

**Broad intellectual property portfolio.** The Company believes that it has a strong IP portfolio with patents issued and others pending worldwide, covering composition of matter, methods of use and manufacturing processes for each of its compounds.

**Strong leadership team.** ZIOPHARM's management team includes a variety of seasoned individuals with significant development and commercialization capabilities and industry experience.

**Distinguished Medical Advisory Board.** The Company's Medical Advisory Board (MAB) is comprised of world leaders in adult and pediatric oncology, translational medicine and drug development, several of whom are current or former Presidents of ASCO and ECCO. The MAB includes: James Armitage, MD, Joseph Bertino, MD, George Demetri, MD, Lawrence Einhorn, MD, John Smyth, MD, Alberto Pappo, MD, David Spriggs, MD, and Alan Houghton, MD.

## LEADERSHIP TEAM

Executive	Relevant Years Experience
<b>Jon Lewis, MD, PhD - Chief Executive Officer, Chief Medical Officer</b> Yale, Memorial Sloan-Kettering, Antigenics (CMO)	17
<b>Dick Bagley - President, Chief Operating Officer</b> Biotech CEO (Velcade®, OvaRex®), Pres. Squibb US, SmithKline (Tagamet®)	40
<b>Barbara Wallner, PhD - Chief Technology Officer</b> Biogen (Amevive®), ImmuLogic, Point Therapeutics, BioTransplant	26
<b>Barry Jones, PhD - SVP, Technical Operations</b> Point Therapeutics, Procept	15
<b>Bob Morgan, JD - SVP, Regulatory Affairs, Quality, and Clinical Development</b> EPIX, Theseus, DuPont, Genzyme, PAREXEL	22
<b>John Amedio, PhD - VP, Manufacturing Process Development</b> EPIX, Sandoz (Novartis)	17
<b>Steve Bloom - VP, Business Development</b> Eli Lilly (Prozac®), Inflexxion, PHARMetrics, PAREXEL	24
<b>Jan Stevens, RN - VP, Clinical Operations</b> Therion Biologics, Antigenics, CareStat Inc., Harvard University Health Services	20

# PRODUCT CANDIDATES

**Palifosfamide (ZIO-201)** is a proprietary stabilized formulation of isophosphoramidate mustard (IPM), the active metabolite of ifosfamide. Currently there are two lyophilized injectable salt formulations and one oral formulation of palifosfamide. Ifosfamide is an alkylating drug used to treat diverse cancers including testicular cancer, sarcoma, and lymphoma. Palifosfamide delivers only the cancer fighting component of ifosfamide without the two toxic metabolites of the parent drug that cause the debilitating side effects of “fuzzy brain” (encephalopathy) and severe bladder toxicity. Palifosfamide is currently in a Phase II randomized controlled trial with doxorubicin in patients with unresectable or metastatic soft-tissue sarcoma (PICASSO trial). A single agent Phase II clinical trial in sarcoma has been completed and awaiting final data, a Phase I soft-tissue sarcoma combination trial with doxorubicin (Adriamycin®) is nearing completion, and an oral study is planned.

**Indibulin (ZIO-301)** is a novel, unique targeted tubulin binding agent. It targets both mitosis and seeding. Indibulin has several advantages including: 1) oral dosing, 2) potential application in multi-drug resistant tumors, 3) no neuropathy at curative doses in animals and 4) minimal overall toxicity. Composite data for indibulin’s two Phase I trials was presented in July 2008 and two separate Phase I/II studies are currently underway, one in combination with Tarceva® and the other in combination with Xeloda®.

**Darinaparsin (ZIO-101)** is a novel organic arsenic being developed for the treatment of various hematologic and solid cancers. Darinaparsin is being developed with the goal of avoiding toxic side effects and potentially expanding the application of this novel class of agents to a wide array of cancer indications. Unlike inorganic arsenic, preclinical and clinical studies show little serious toxicities associated with organic arsenic, particularly the ECG abnormalities seen at high doses. Extensive ECG data has been collected as part of the darinaparsin development program and central tendency analysis revealed no significant drug effect on cardiac function comparable to inorganic arsenic. A Phase II trial is nearing completion in patients with primary liver cancer and advanced myeloma, a Phase II trial is ongoing in patients with lymphomas, and a Phase I oral trial is in progress.

## Palifosfamide : Clinical Development Plan

	Preclinical	Phase I	Phase II	Phase III
Advanced Sarcoma				
Combination Adriamycin® (doxorubicin)			Final Data 2H08	
Oral				
Phase II RCT	Q3			

## Indibulin: Clinical Development Plan

	Preclinical	Phase I	Phase II	Phase III
Oral Single Agent			Composite Data Presented in July	
Other POC Studies				
Combination Tarceva® (erlotinib)			Data 1H 2009	
Combination Xeloda® (capecitabine)				
Potential Phase II RCT	Late 2009			

## Darinaparsin: Clinical Development Plan

	Preclinical	Phase I	Phase II	Phase III
Myeloma				Publication
Leukemia/Lymphoma				Enriched Data 2H08
Hepatocellular Carcinoma				Accrual Completed
Oral		Initial Data 2H08		

# UPCOMING MILESTONES

Compound	Goal	Target
<b>Palifosfamide (ZIO-201)</b>	Initiate IV Ph I/II combination doxorubicin trial	achieved '09
	Initiate oral Ph I solid tumors	'09
	Final Ph II sarcoma data (refractory)	2H '08
	Ph I combination doxorubicin	2H '08
	Initiate Randomized front- & second-line Ph II sarcoma	achieved
	Randomized Phase II data	2H '09
<b>Indibulin (ZIO-301)</b>	Initiate Ph I/II combination Tarceva® trial	achieved
	Initiate second Ph I/II Xeloda® trial	achieved
	Final composite data from three Ph I trials	achieved
	Data from two combination trials	1H '09
	Potential randomized Phase II	2H '09
<b>Darinaparsin (ZIO-101)</b>	Final Ph II myeloma	written publication
	Final Ph II heme	2H
	Preliminary Ph II liver	2H
	Preliminary oral Ph I	2H

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Some of the statements made in this document are forward-looking statements. These forward-looking statements are based upon our current expectations and projections about future events and generally relate to our plans, objectives and expectations for the development of and commercialization of in-licensed cancer drugs. Although management believes that the plans and objectives reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties and actual future results may be materially different from the plans, objectives and expectations expressed in this document.