

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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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): **September 7, 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)

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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)).
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).
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**Item 8.01 Other Events**

ZIOPHARM Oncology, Inc., or the Company, will present the attached discussion of the Company's palifosfamide development strategy and milestones, as well as the Company's IL-12 DNA therapeutics program, at the BioCentury NewsMakers in the Biotech Industry Conference in New York, New York, being held on September 7, 2012.

A copy of the above referenced presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Presentation of the Company dated September 7, 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.

By: /s/ Jason A Amello

Name: Jason A Amello

Title: Executive Vice President and Chief Financial Officer

Date: September 7, 2012

**INDEX OF EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Presentation of the Company dated September 7, 2012



**ZIOPHARM Oncology**

**Better Cancer Medicine**

19<sup>th</sup> Annual NewsMakers in the Biotech Industry Conference

[www.ziopharm.com](http://www.ziopharm.com)

September 7, 2012 | 1

## Forward-Looking Statements

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This presentation contains certain forward-looking information about ZIOPHARM Oncology 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 any of our therapeutic candidates 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 any of our therapeutic candidates 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 reports filed with the SEC 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. Our audience is 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.

## Our Approach

Early to  
Late-Stage  
Small  
Molecules

DNA-Based  
Therapeutics

Revolutionary  
Discovery  
Technology  
Poised to  
Cure Cancers

Diverse Portfolio of Therapeutics Addressing  
Unmet Medical Needs in Cancer

*Better Cancer Medicine*

## 2012 Anticipated Key Clinical Milestones

### Palifosfamide

**PICASSO 3**  
STS Pivotal PFS Data 4Q 2012

**MATISSE**  
SCLC Phase 3 Initiation 2Q 2012

### DNA Therapeutics

**IL-12 DNA Program**  
Phase 1 Data 2012

Phase 2 Melanoma 2H 2012

New DNA Candidates  
• Preclinical Data 2012

### Early Stage Small Molecule Pipeline

Indibulin: Oral Phase 1/2 Data  
Darinaparsin: Ongoing Studies with Solasia





## Near-Term Value Drivers

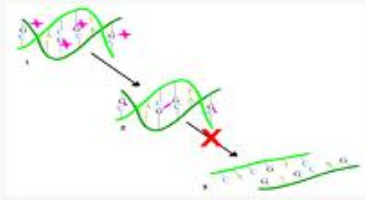
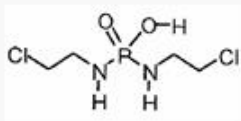
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- Palifosfamide
  - Wholly-owned asset
  - Two Phase 3 programs
    - Metastatic soft tissue sarcoma
    - Small cell lung cancer
  - Potential in multiple solid tumor types
- DNA therapeutics
  - Targeting established pathways
  - Approaching Phase 2 for melanoma
  - Exploring multiple avenues for revolutionary treatment modality

# Palifosfamide

## A Novel DNA-Targeted Drug

<b>Broad Application</b>	Effect in solid tumors and hematological malignancies
<b>Safety, Efficacy and Accessibility</b>	Active in ALDH <sup>hi</sup> cells, rapid on-off kinetics, less toxic and ease of administration
<b>Addressing Unmet Needs</b>	Orphan Drug status for STS in U.S. and Europe
<b>Long Commercial and Development Runway</b>	U.S. pharmaceutical composition patent rights extending to 2029; other pending applications WW



## Soft Tissue Sarcoma

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- High unmet medical need; no first-line drug approved in ~30 years
- First-line metastatic, non-GIST STS:<sup>1</sup>
  - Approximately 9,000 in U.S.<sup>2</sup>
  - Approximately 14,000 in Europe
- Market in transformation
  - April 2012 FDA full approval of Votrient® for second-line therapy validate PFS endpoint; May 2012 positive opinion from CHMP
- Objective of palifosfamide in combination with doxorubicin as standard of care for first-line metastatic STS

<sup>1</sup> Source: U.S.: IntrinsiQ Data, © Copyright 2012, IntrinsiQ, LLC an AmersourceBergen Specialty Group company. All rights reserved; remainder of world Company estimated from epidemiology (SEER, NCCN).

<sup>2</sup> IntrinsiQ: # new patient prescriptions written for first-line, non-GIST STS over 12 months.

## Phase 3 Structure (PICASSO 3)

*Design Based on Successful Randomized Phase 2 Study with Similar Design*

N:	<b>Fully Enrolled</b> - Approximately 424 patients; first-line metastatic STS
Regimen:	Palifosfamide + doxorubicin vs. doxorubicin + placebo
Primary Endpoint:	PFS for accelerated approval; OS for full approval Powered for PFS & OS
PFS Power:	85% power to detect 0.60 HR, 3 month median $\Delta$ ( $p=0.0005$ , one-tailed)
PFS Analysis:	Evaluation of PFS by IDMC following a pre-determined number of PFS events
Study sites:	> 150 centers worldwide
<b>Results:</b>	<b>Pivotal PFS data expected 4Q 2012</b>

## Small Cell Lung Cancer

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- High unmet medical need; little innovation in decades
- Worldwide market opportunity: 250,000+ patients<sup>1</sup>
  - 30,000 -35,000 patients in the U.S.
- Rationale: ifosfamide only first-line therapy to show benefit added to SOC (platinum plus etoposide)
  - Excessive toxicity<sup>2</sup>
- Palifosfamide added to SOC demonstrating early success in highly refractory patients
  - Combination well tolerated
- **Phase 3 study enrolled first patient June 2012**

<sup>1</sup>SEER, Globocan.  
<sup>2</sup>Hoosier Oncology Group - Einhorn et. al.

## Phase 3 in SCLC (“MATISSE”)

*The MATISSE Study: **M**ulticenter **A**daptive **T**rial **I**nvestigating **S**mall Cell Lung Cancer **S**urvival **E**ndpoints*

<b>Design</b>	Multinational, multi-center, randomized controlled, open-label, adaptive trial
<b>N</b>	Up to 548 subjects
<b>Population</b>	Males and females, age $\geq 18$ years, with extensive-stage small cell lung cancer
<b>Primary Endpoint</b>	Overall survival (OS)
<b>Secondary Endpoints</b>	Progression free survival (PFS) Objective response rate (ORR) Quality of Life (QOL) Disease related symptoms





***Single pre-planned  
evaluation by the IDMC***

- *Optimize chances of success*
- *Stop trial for efficacy/futility*
- *Complete trial as planned or resize study*



**ZIOPHARM Oncology**

# **Palifosfamide** **Market Opportunity**

## STS Market Position

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- No uniform standard of care for first-line in U.S. market<sup>1</sup>
  - *Opportunity to consolidate* the market within 24 months after launch<sup>2</sup>
- EU market primarily ifosfamide and/or doxorubicin<sup>3</sup>
- Palifosfamide could become new standard of care in first-line metastatic, non-GIST STS<sup>2</sup>
  - Better efficacy profile
  - Better safety profile
  - Outpatient administration
  - Better health economic profile

<sup>1</sup>Source: U.S.: IntrinsicQ Data, © Copyright 2012, IntrinsicQ, LLC an AmersourceBergan Specialty Group company. All rights reserved.

<sup>2</sup>High prescribing STS market research; Hammond Hill, LLC 2012.

<sup>3</sup>Data on file.



## SCLC Market Position

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- Etoposide plus carboplatin represents ~70% of current SOC<sup>1</sup>
- Goal to establish palifosfamide in combination with etoposide and carboplatin as first-line standard of care in metastatic SCLC

<sup>1</sup>Source: U.S.: IntrinsiQ Data, © Copyright 2012, IntrinsiQ, LLC an AmersourceBergen Specialty Group company. All rights reserved.



## Market Potential

- Recent, U.S. orphan drug launches in oncology priced at \$9K - \$23K per cycle range
  - Examples of products: Adcetris™, Caprelsa®, Istodax®, Zelboraf®

Scenarios of U.S. Only Peak Gross Revenues in \$Million				
	Patients Treated	Palifosfamide Price Per Patient Per Year		
		\$ 54,000	\$ 72,000	\$ 90,000
Soft Tissue Sarcoma	4,000	\$ 216	\$ 288	\$ 360
	4,500	\$ 243	\$ 324	\$ 405
	5,000	\$ 270	\$ 360	\$ 450
Small Cell Lung Cancer	5,500	\$ 297	\$ 396	\$ 495
	6,500	\$ 351	\$ 468	\$ 585
	7,500	\$ 405	\$ 540	\$ 675

Note: Assumes 6 cycles per patient per year.

- >\$1 Bn total global market potential** for palifosfamide in STS and SCLC

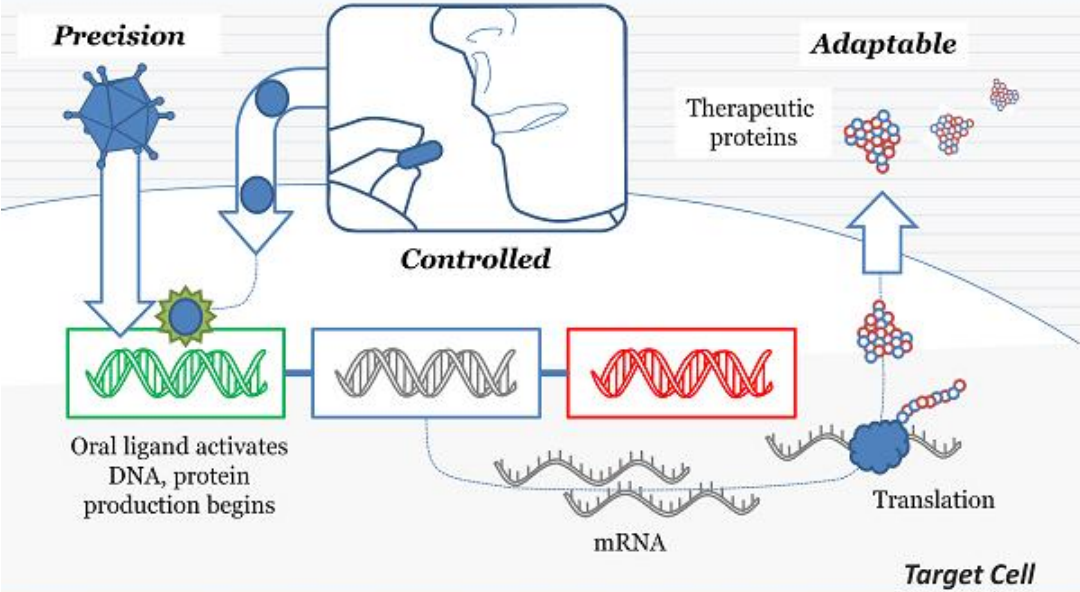
## IL-12 DNA

## DNA Therapeutics

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- Revolutionary technology for precise, controlled delivery of therapeutic proteins *in vivo*
- Focused, disciplined approach to development
  - Minimize expense
  - Drive value through near-term proof-of-concept studies
- Lead therapeutic in melanoma for early validation of target and platform
- “Next-wave” of therapeutic approaches in research pipeline (antibody technology, protein-protein decoys, immunotoxins, etc.)

# Using Natural Cell Biology to Produce Proteins

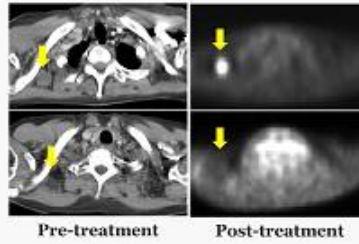




## Two Clinical Stage Product Candidates

- **DC IL-12 Phase 1b in metastatic melanoma**

- Safety profile predictable
- 2 PRs, 2 SDs, biomarker effects



- **Ad IL-12 Phase 1b in metastatic melanoma**

- Safe to date
- Preliminary activity
- **Significant data expected 2H 2012**



## Phase 1/2 of Ad-IL12 + AL in Melanoma

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### Next Phase of Development:

- Remains a *significant unmet need* in metastatic melanoma despite evolving landscape
- Phase 2 to begin at confirmation of biologically effective dose
- Phase 2 modifications to include additional patient-selection criteria to maximize signal detection
- ***Planned to be completed 1H 2013***

### Will inform additional studies and development plans:

- Breast Cancer
- Head and neck cancer



# Early-Stage Development

## Early-Stage Clinical Development

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### **DNA Therapeutics**

- Preclinical and discovery continuing to advance multiple antibody, immunotoxin, and protein decoy candidates
- INDs next 12 to 24 months from preclinical work in progress

### **Indibulin**

- Novel oral tubulin binding agent; expected low toxicity and neurotoxicity not seen
- Ongoing Phase 1/2 study in metastatic breast cancer

### **Darinaparsin**

- Novel mitochondrial- and hedgehog-targeted agent (organic arsenic); oral and IV
- Ongoing studies in partnership with Solasia



## Financial Highlights

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- Primary shares outstanding: approximately 79.6M
- Cash: approximately \$110.4M @6/30/12
- Current cash resources expected to support operations into 2H 2013

## 2012 Anticipated Key Clinical Milestones

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September 7, 2012 | 27

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