
**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): **March 13, 2013**

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
20th 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:

- 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 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 synthetic biology program, at the Barclays Global Healthcare Conference in Miami, Florida, being held on March 13, 2013.

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 March 13, 2013

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, Chief Financial
Officer and Treasurer

Date: March 13, 2013

INDEX OF EXHIBITS

**Exhibit
No.**

Description

99.1 Presentation of the Company dated March 13, 2013



ZIOPHARM Oncology

Better Cancer Medicine

Barclays Global Healthcare Conference

Jonathan Lewis, MD, PhD
Chief Executive Officer

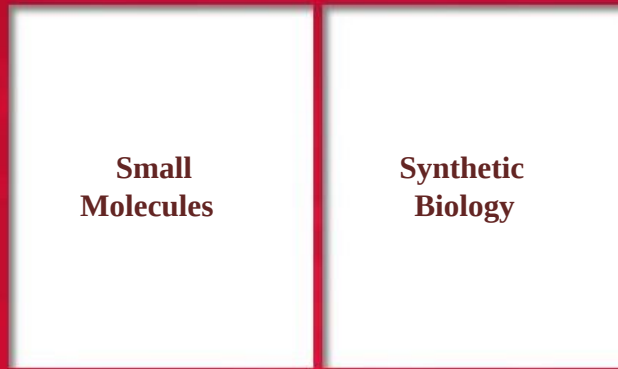
www.ziopharm.com

March 13, 2013 | 1

Forward-Looking Statements

This presentation contains certain forward-looking statements about ZIOPHARM Oncology that are 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)”, “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; our expectations regarding approval for our products by the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; estimates regarding the market potential for our products; 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 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 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 pharmaceutical and biotechnology companies; the development of and our ability to 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 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 September 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.

**Paradigm Shifting Approaches
to Impact and Cure Cancer**



**Diverse Portfolio of Therapeutics Addressing
Unmet Medical Needs in Cancer**

Better Cancer Medicine

Data-Driven Oncology Portfolio

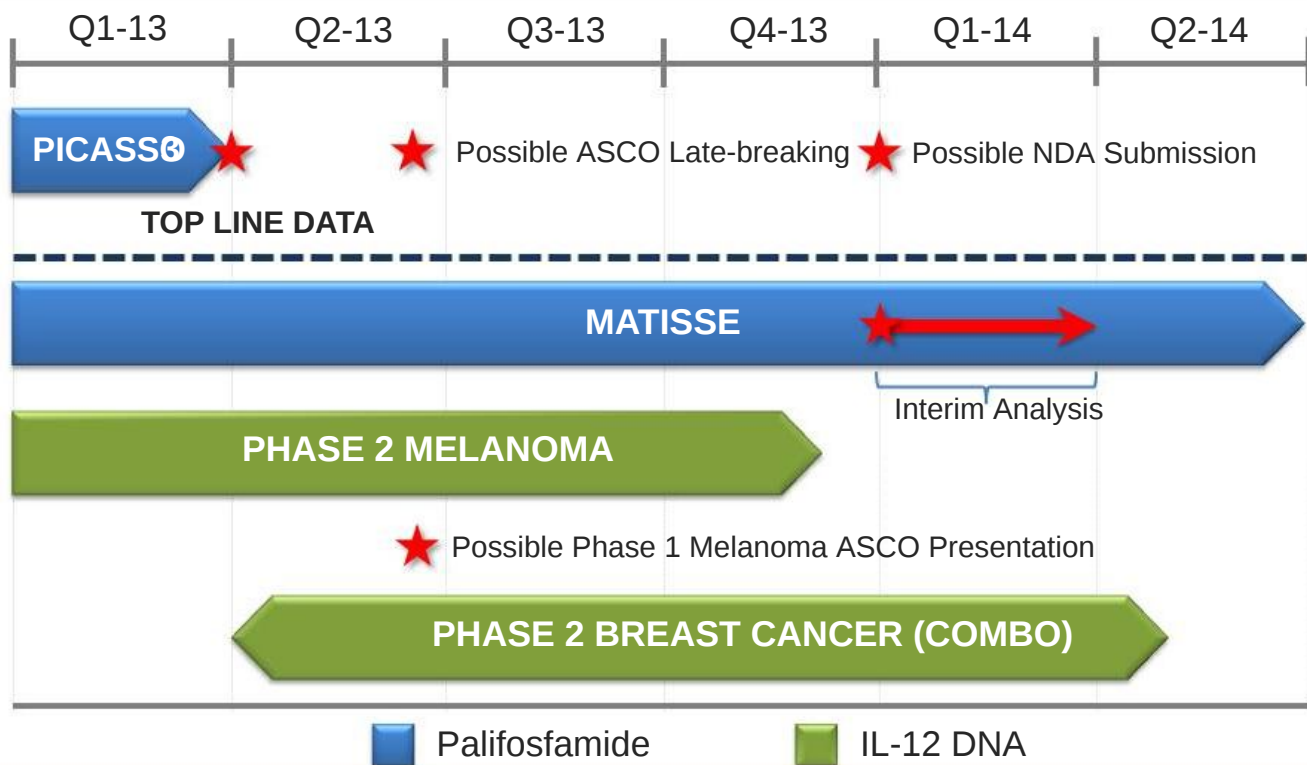
Compound	Preclinical	Phase 1	Phase 2	Phase 3
Palifosfamide				
Soft Tissue Sarcoma	[Blue bar spanning from Preclinical to Phase 3]			
Small Cell Lung Cancer	[Blue bar spanning from Preclinical to Phase 2]			
Oral Formulation	[Blue bar spanning from Preclinical to Phase 1]			
Ad-RTS-IL-12				
Melanoma	[Green bar spanning from Preclinical to Phase 2]			
Breast (+palifosfamide)	[Green bar spanning from Preclinical to Phase 2]			
Other Candidates	[Green bar spanning from Preclinical to Phase 1]			
Indibulin				
Breast Cancer	[Red bar spanning from Preclinical to Phase 1]			
Darinaparsin				
PTCL	[Cyan bar spanning from Preclinical to Phase 2]			

Near-Term Value Drivers

- Palifosfamide
 - Two Phase 3 programs
 - Metastatic soft tissue sarcoma
 - Small cell lung cancer
 - Potential in multiple tumor types
 - Exceptional intellectual property profile (t0 2029)

- Synthetic Biology
 - Two Phase 2 programs
 - Melanoma
 - Breast cancer
 - Exploring multiple opportunities for new-paradigm treatment modality
 - Controlled switch for *in vivo* protein production

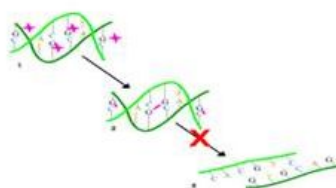
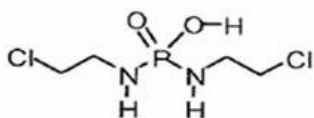
Major Clinical Milestones Over Next 18 Months



Palifosfamide

A Potent Bi-Functional DNA Alkylating Agent

Broad Application	Effect in solid tumors and hematological malignancies
Safety, Efficacy and Accessibility	Potent bi-functional DNA alkylating agent that has activity in multiple tumors by evading typical resistance pathways (in class with bendamustine, cyclophosphamide, and ifosfamide), with low toxicity and ease of administration
Addressing Unmet Needs	Orphan Drug status established for STS in U.S. and Europe
Exceptional Intellectual Property Profile	U.S. pharmaceutical composition patent rights extending to 2029; other pending applications WW



Soft Tissue Sarcoma

- High unmet medical need; no first-line drug approved in ~30 years
- First-line metastatic, non-GIST STS: ¹
 - Approximately 9,000 in U.S. ²
 - Approximately 14,000 in Europe
- Market in transformation
 - April 2012 FDA full approval of Votrient [®] for second-line therapy (PFS endpoint); August 2012 European full approval

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

² IntrinsicQ: # new patient prescriptions written for first-line, non-GIST STS over 12 months.

EOP2 Meeting¹

- December 18, 2007:
- SPA recommended but not pursued by applicant
- If PFS used as primary endpoint:
 - The study should be powered for OS
 - Independent blinded radiologic review committee
 - Magnitude of PFS effect should be robust
 - Appropriate risk benefit ratio

¹Votrient® ODAQ March 20, 2012

Phase 3 Design (PICASSO 3)

N:	447 subjects; first-line metastatic STS
Regimen:	Palifosfamide + doxorubicin vs. placebo + doxorubicin
Primary Endpoint:	PFS for full approval
Powering:	Powered for both PFS and OS
PFS Analysis:	Independent blinded radiologic review; Efficacy analysis by IDMC IDMC following pre-determined number of PFS events
Results:	Pivotal topline PFS data, OS futility analysis (OS remains blinded) to be announced week of March 25, 2013

Regulatory Strategy: Evolving Landscape of PFS as Primary Endpoint

- PFS primary endpoint in Phase 3 registration trials and now supportive for certain indications:
 - In 2011, 4 oncology products approved based on PFS as primary trial endpoint
 - In 2012, 7 oncology products approved based on PFS as primary trial endpoint, including pazopanib (Votrient[®]) receiving full approval for STS

Multicenter, Randomized, Stratified, Balanced Phase 2 Data (PICASSO)

	<i>Arm A: Pali+Dox</i>	<i>Arm B: Dox**</i>
PFS: median	7.8 mos.	4.4 mos.
PFS: hazard ratio	0.43	
OS: hazard ratio (<i>with crossover</i>)	0.78	
2-yr survival (<i>with crossover</i>)*	40%	30%
Safety	<ul style="list-style-type: none"> • Similarity between arms • <u>No</u> encephalopathy, hemorrhagic cystitis, Fanconi's Syndrome 	
Grade 3+ events	<ul style="list-style-type: none"> • Neutropenia and elevated creatinine (<i>similar between arms</i>) 	

Phase 3: Correctly Modeled and Powered for PFS & OS

Source: Best of ASCO 2010 (PFS Data), internal analysis (OS Data)

* Expected 2-yr survival is 25% based on evaluation of randomized data

** Control arm confirmed by EORTC ifosfamide vs doxorubicin study, ESMO 2012

EORTC 62012 Randomized Phase 3 Trial (ESMO)

	PICASSO		EORTC	
	Pali+Dox	Dox	Ifos+Dox	Dox
PFS: median	7.8 mos.	4.4 mos.	7.4 mos.	4.6 mos.
PFS: hazard ratio	0.43		0.74	
OS: hazard ratio (<i>with crossover</i>)	0.78		2yr. N/A (mOS: 0.83)	
2-yr survival	40%	30%	31%	28%
Safety	<ul style="list-style-type: none"> • Similarity between arms • <u>No</u> encephalopathy, hemorrhagic cystitis, Fanconi's Syndrome 		<ul style="list-style-type: none"> • Dropouts for toxicity 17.6% (I+D) vs. 2.6% (D) (including toxic death) 	
Grade 3+ events	<ul style="list-style-type: none"> • Neutropenia and elevated creatinine (similar between arms) 		<ul style="list-style-type: none"> • Febrile Neutropenia 45.9% (I+D) vs. 13.6% (D) 	

Appropriate Risk/Benefit Ratio Is Critical

Small Cell Lung Cancer

- High unmet medical need; no innovation in decades
- Worldwide market opportunity: 250,000+patients¹
 - 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 toxicity²
- Palifosfamide added to SOC demonstrating early success in highly refractory patients - combination well tolerated

¹SEER, Globocan.

²Hoosier Oncology Group - Einhorn et. al.



*Single pre-planned
evaluation by the IDMC*

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



MATISSE Trial Progress

- *MATISSE* trial enrollment **ahead** of projection
- Successful IDMC safety review of initial 20 patients
- Interim analysis of 125 events expected end of 2013

Market Potential

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

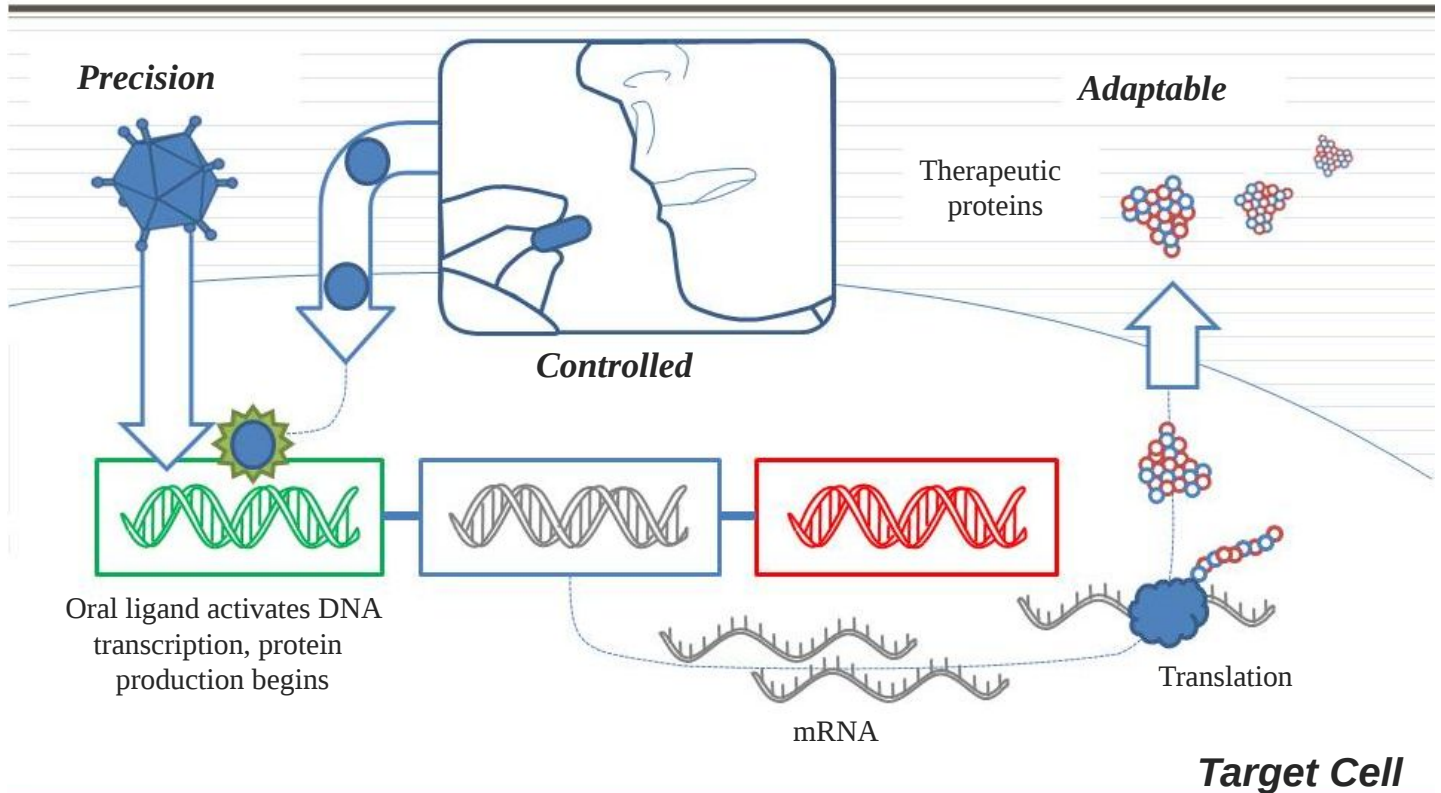
Scenarios of U.S. Only Peak Gross Revenues in \$Million				
	Patients Treated	Palifosfamide Price Per Patient Per Year		
		\$ 54,000	\$ 72,000	\$ 90,000
Soft Tissue Sarcoma	4,000	\$ 216	\$ 288	\$ 360
	4,500	\$ 243	\$ 324	\$ 405
	5,000	\$ 270	\$ 360	\$ 450
Small Cell Lung Cancer	8,000	\$ 432	\$ 576	\$ 720
	10,000	\$ 540	\$ 720	\$ 900
	12,000	\$ 648	\$ 864	\$ 1,080

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

Synthetic Biology

- Revolutionary technology for precise, controlled delivery of DNA expressing therapeutic proteins *in vivo*
- Lead Ad-RTS-IL-12 candidate in melanoma, breast cancer
- Next generation of therapeutic approaches in research pipeline
 - Modular inducible cancer immunotherapy (MICI)
 - Antibody therapy
 - Multigenic approaches

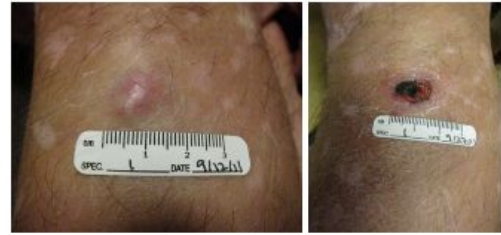
Using Natural Cell Biology to Produce Proteins: Adenoviral Approach



Phase 1/2 Ad-RTS-IL-12 Candidate

- **Ad-RTS-IL-12 Phase 1b in metastatic melanoma**
 - Biologically effective dose was determined
 - Clinical activity observed in 71% of patients (n=7), two highest dose cohorts
 - No dose-limiting toxicity reported to date

- **Ad-RTS-IL-12 Phase 2 in metastatic melanoma**
 - Multi-center, single-arm, open-label expansion stage study
 - Enrolling up to 15 patients



Baseline

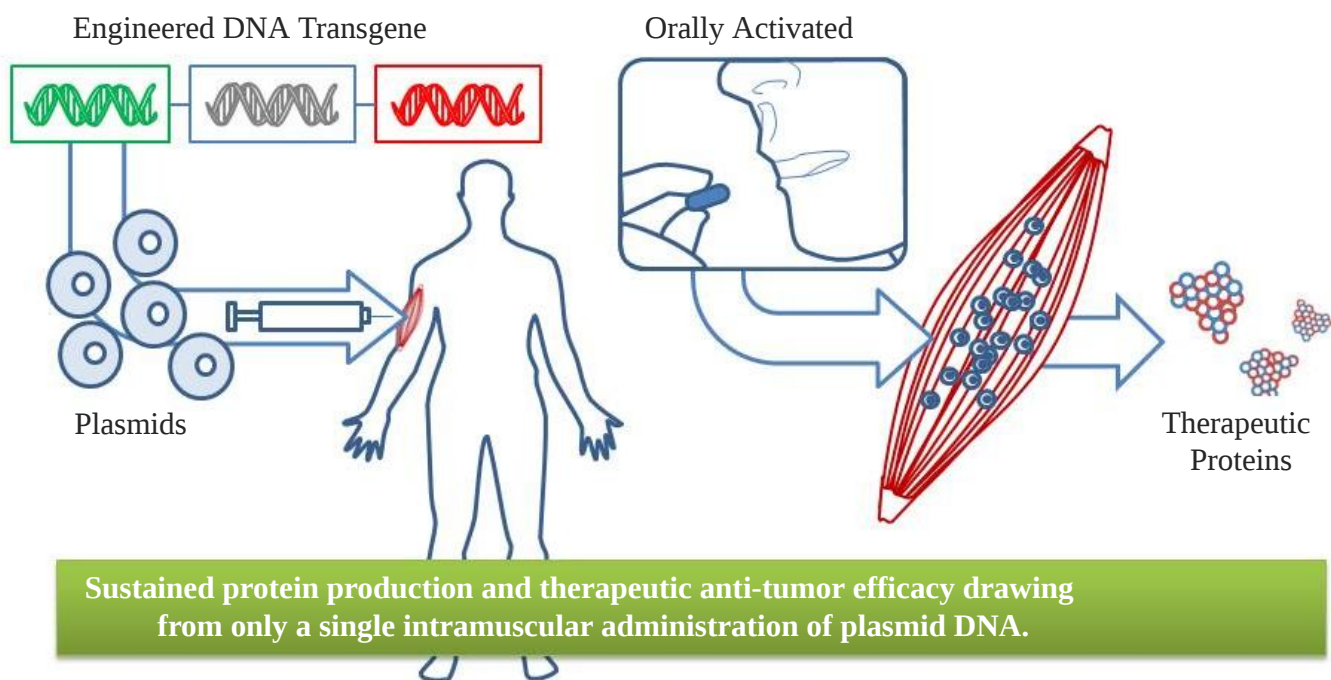
Necrosis prior
to cycle 2

Phase 2 Breast Cancer

Ad-RTS-IL-12 + palifosfamide

Design	Randomized, open-label study of Ad-RTS-IL-12 monotherapy or combination with palifosfamide in patients with recurrent/metastatic breast cancer and accessible lesions
N	Up to 68 subjects
Population	Recurrent/metastatic breast cancer
Primary Endpoint	16-week PFS rate
Select Secondary Endpoints	<ul style="list-style-type: none">• Objective response rate by modified RECIST v1.1• Duration of response• Evaluate pharmacodynamic tumor markers
Outcome	<ul style="list-style-type: none">• Changing regulatory landscape of breast cancer• Acceptance of pCR (pathologic CR) as a validated endpoint for accelerated approval in neoadjuvant setting• Potential rapid positioning of this combination from refractory to neoadjuvant setting

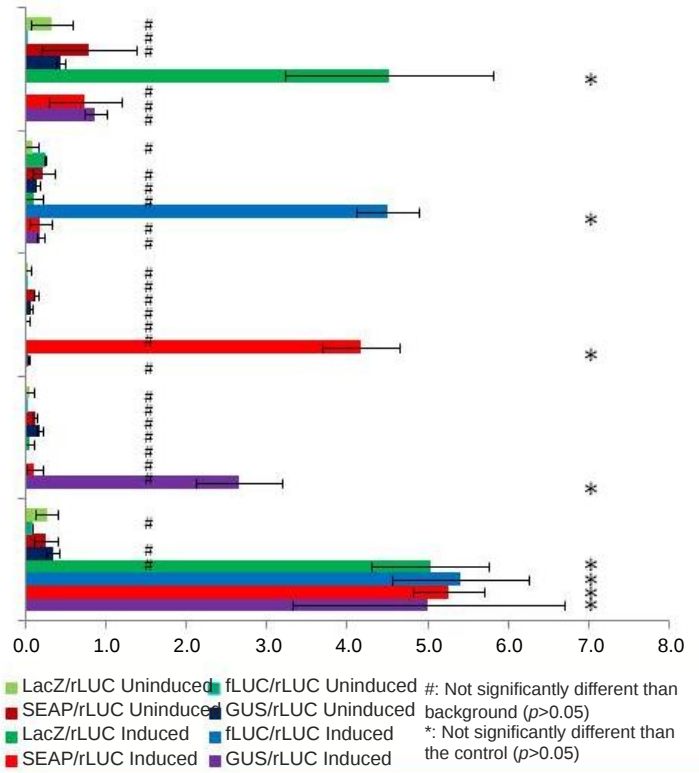
Using Synthetic and Natural Cell Biology to Produce Proteins: Intramuscular Plasmid DNA



EORTC-NCI-AACR International Conference on Molecular Targets and Cancer Therapeutics 2012 (animal model).



Next Generation: Multigenic Approach



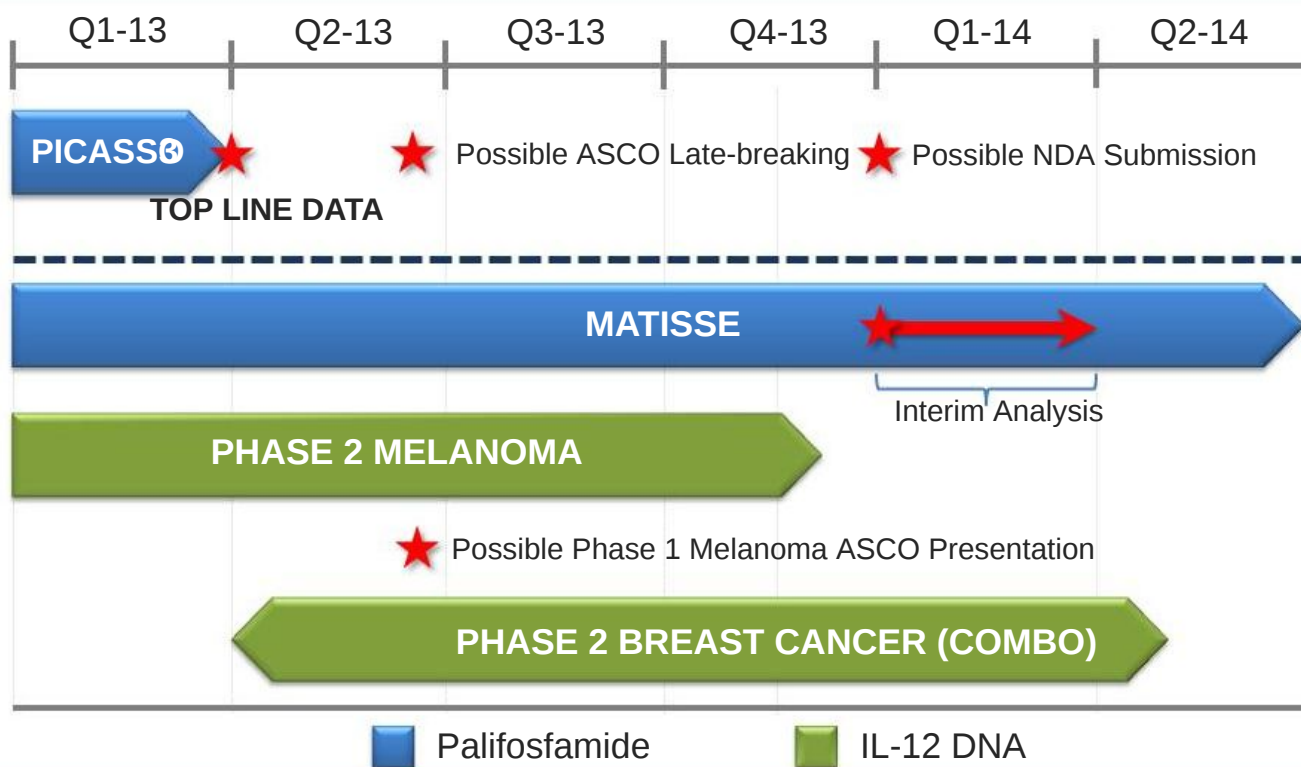
Conclusion:

4 Inducible gene programs can be placed in parallel on the same vector without affecting gene program performance

Financial Highlights

- Primary shares outstanding: approximately 83.2M
- Cash: approximately \$95.3M @ 9/30/12
- Current cash resources expected to support operations into 2H 2013

Major Clinical Milestones Over Next 18 Months





ZIOPHARM Oncology

Better Cancer Medicine

Barclays Global Healthcare Conference

Jonathan Lewis, MD, PhD
Chief Executive Officer

www.ziopharm.com

March 13, 2013 | 28