
**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): May 29, 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.)

One First Avenue, Parris Building 34, Navy Yard Plaza
Boston, Massachusetts
(Address of Principal Executive Offices)

02129
(Zip Code)

(617) 259-1970
(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)).
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Item 8.01 Other Events

ZIOPHARM Oncology, Inc., or the Company, will present the attached discussion of the Company's DNA-based therapeutics at the Deutsche Bank 38th Annual Healthcare Conference in Boston, Massachusetts, being held on May 29, 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 May 29, 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/ Caesar J. Belbel

Name: Caesar J. Belbel

Title: Executive Vice President and Chief Legal Officer

Date: May 29, 2013

INDEX OF EXHIBITS

**Exhibit
No.**

Description

99.1 Presentation of the Company dated May 29, 2013



ZIOPHARM Oncology

Better Cancer Medicine

Deutsche Bank 38th Annual Healthcare Conference

Jonathan Lewis, MD, PhD
Chief Executive Officer

www.ziopharm.com

May 29, 2013

Forward-Looking Statements

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, 2012, and our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2013. 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.



ZIOPHARM Oncology

DNA Therapeutics

*Using the power of DNA to treat
and prevent cancer*

www.ziopharm.com

May 29, 2013

DNA-Based Therapeutics

- Paradigm-shifting, synthetic biology technology for precise, controlled delivery of therapeutic proteins *in vivo*
- *Engineered* approach to product design allows us to rapidly develop new genetically-based treatments for cancer with multiple effectors
- Focused, disciplined and iterative approach to development decreases risk through:
 - Early “go/no go” decisions
 - Fast proof-of-concept and preclinical validation
 - Creating a *virtuous circle* of product development and improvement
 - Minimizing expense
- Lead candidate, Ad-RTS-IL-12 in Phase 2 clinical trials for melanoma and breast cancer

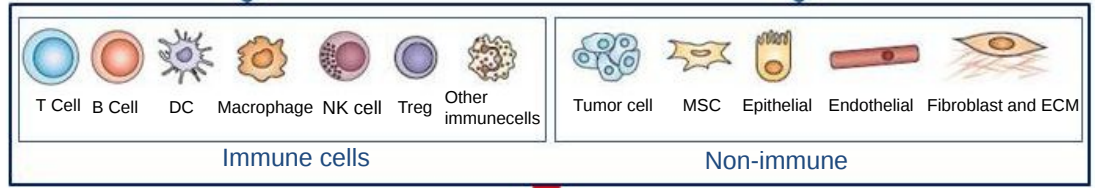


Molecular and Cellular Oncology DNA-Coded Toolset

Effectors



Cells

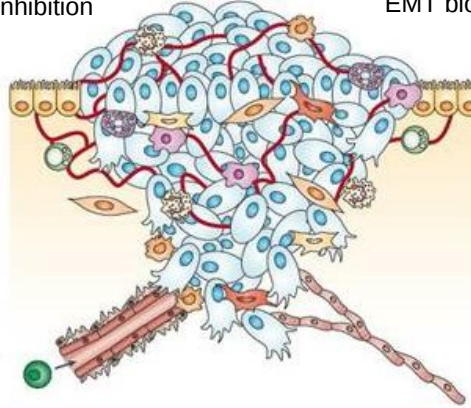


Anti-tumor function

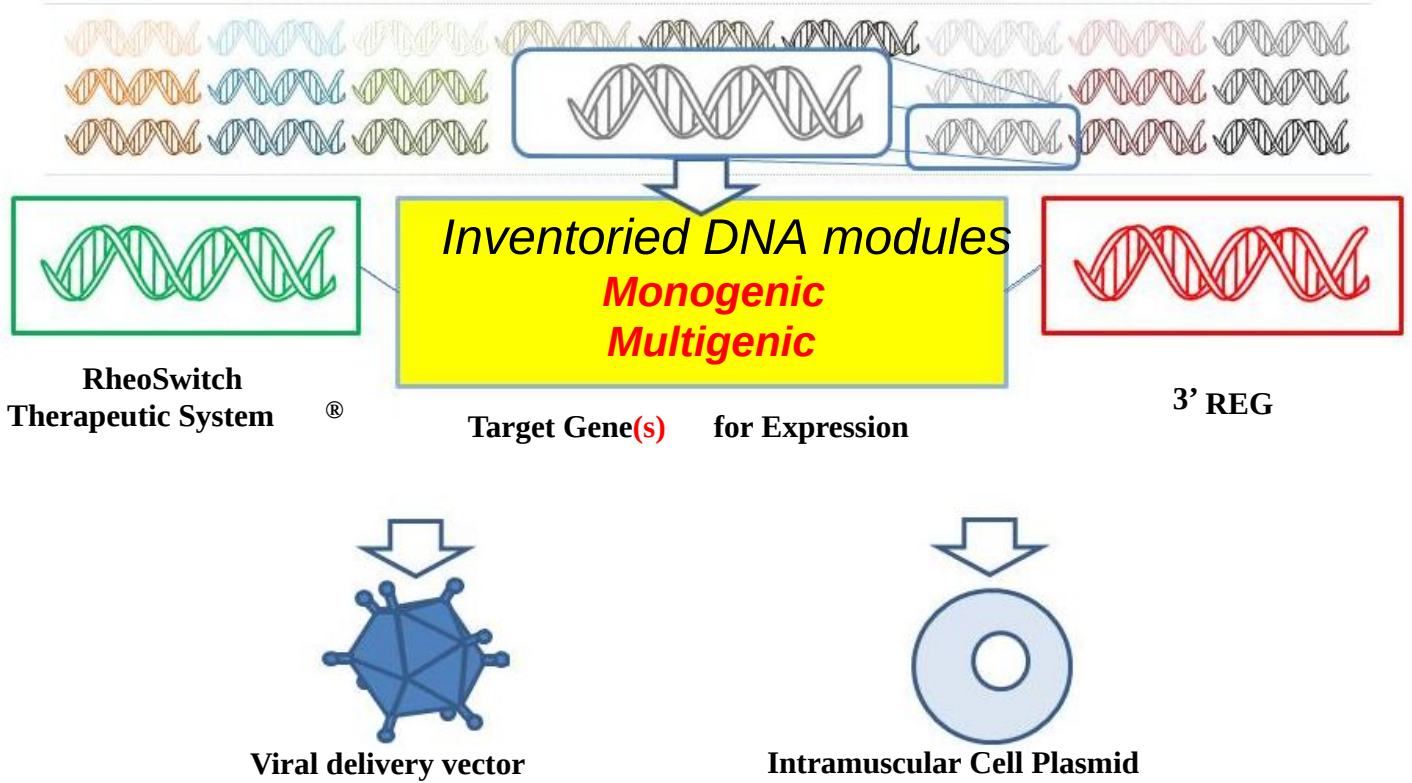
Direct tumor lysis
ADCC
Complement cytotoxicity
Innate immunity stimulation
Adaptive immunity stimulation
Immune evasion inhibition

Pro-apoptosis
Necrosis
Anti-angiogenesis
Growth inhibition
Anti-tumor metabolism
EMT blockade

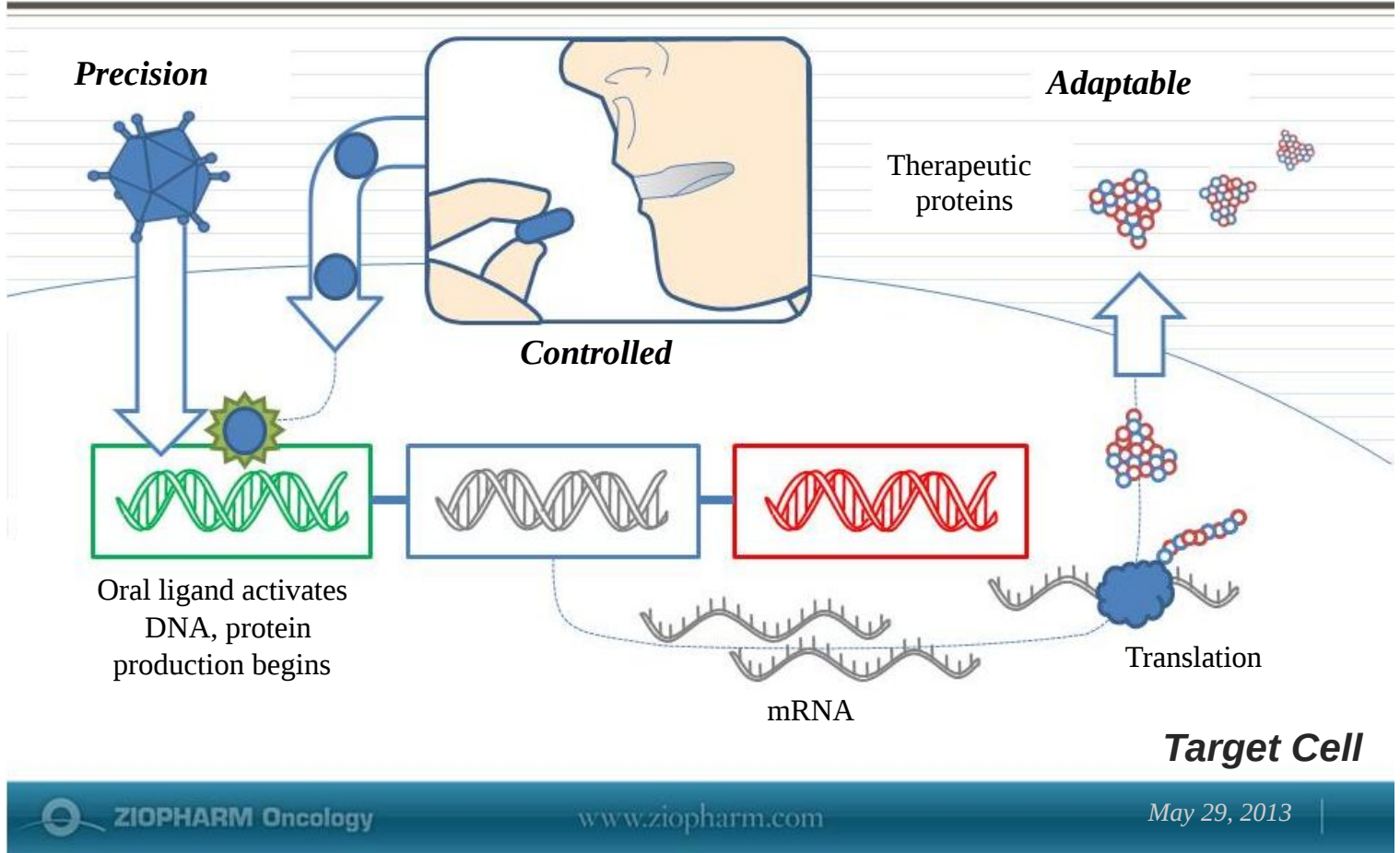
Tumor and microenvironment



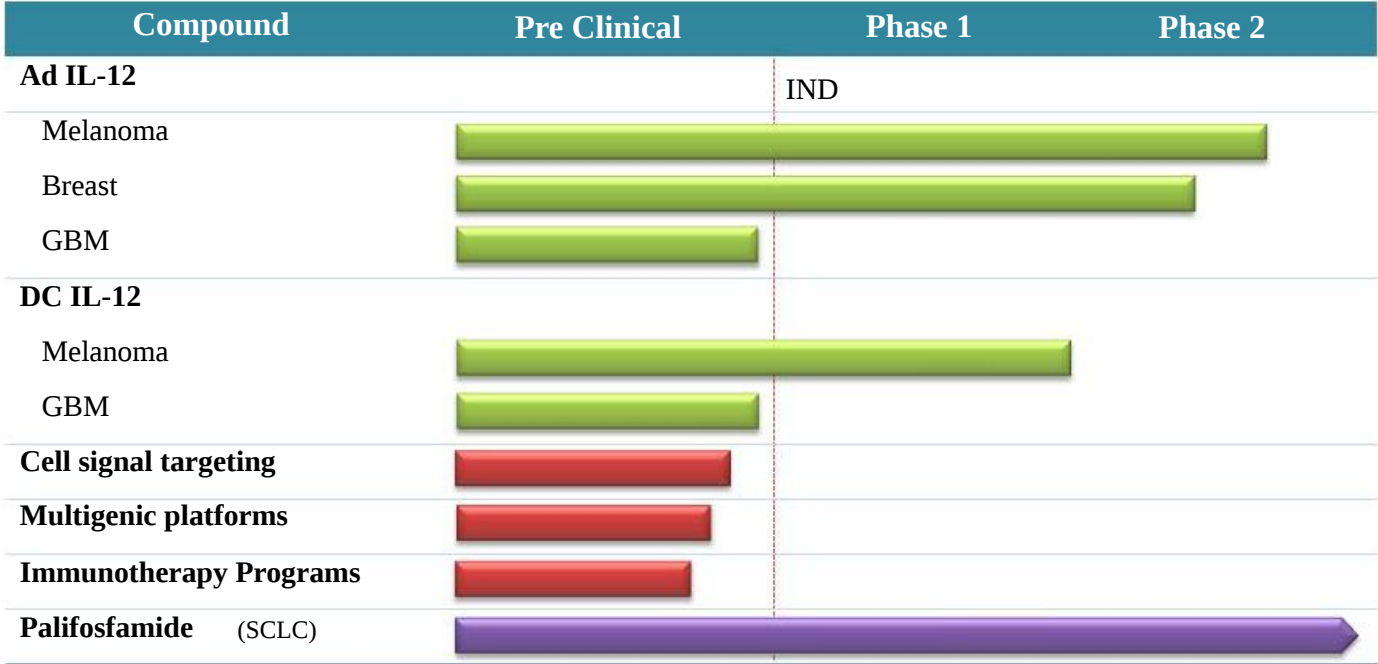
A Platform System for Rapidly Developing Controllable DNA Therapies



Using Natural Cell Biology to Regulate Proteins



Science-Driven Oncology Portfolio



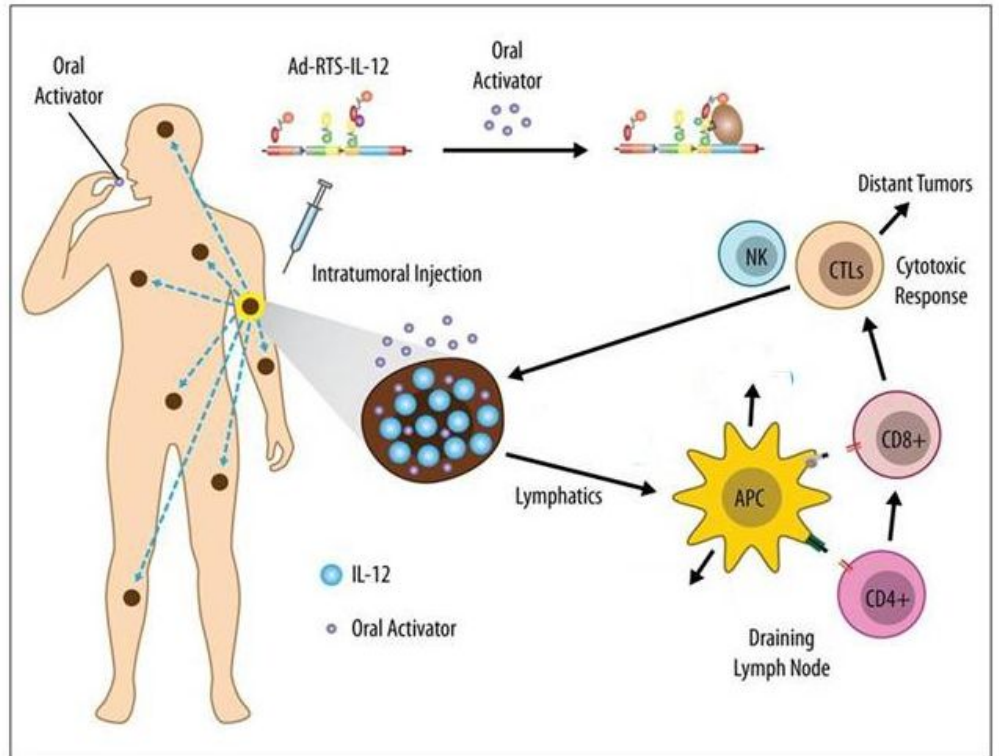
IL-12 Program

Ad-RTS-IL-12

DC-RTS-IL-12

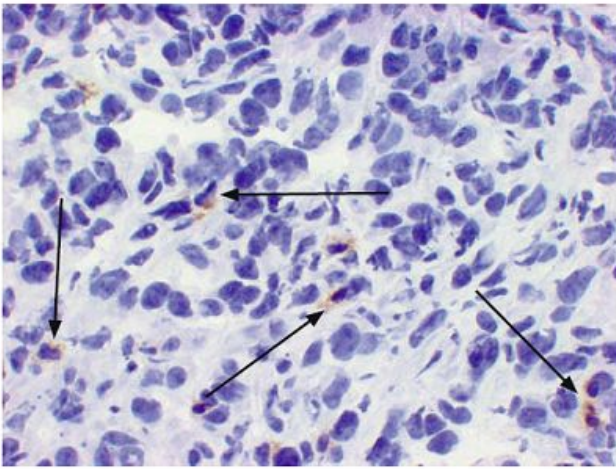
Ad-RTS-IL-12

- Interleukin-12 (IL-12) is a potent, naturally occurring anti-cancer protein central to initiation and regulation of cellular anti-cancer immune responses
- Regulated intratumoral expression of IL-12 promotes activation of TIL's to drive a cytotoxic immune response against distant tumors

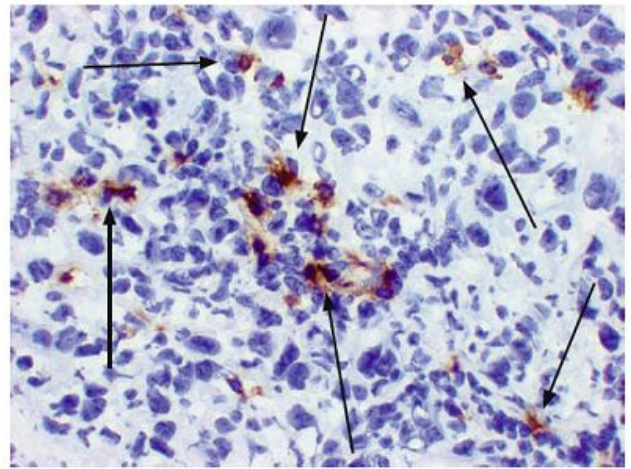


Increases CD8⁺ TILs in the 4T1 Syngeneic Mouse Model

Vehicle

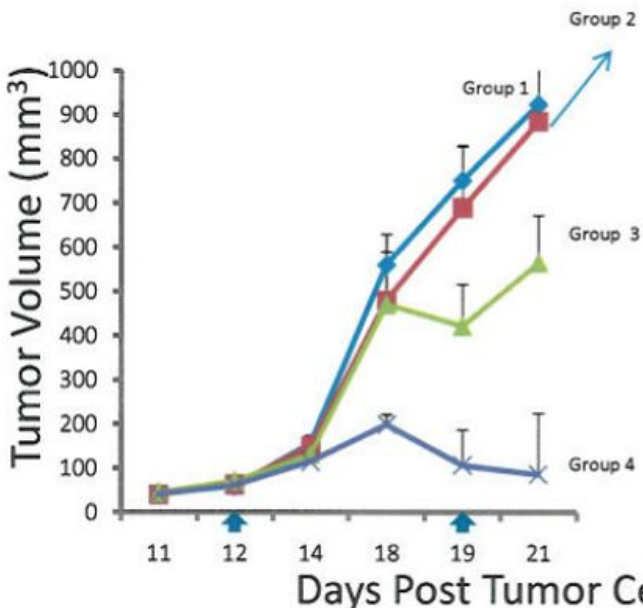


INXN-1001 150 mg/m² +
Ad-RTS-mIL-12 1x10¹⁰ vp

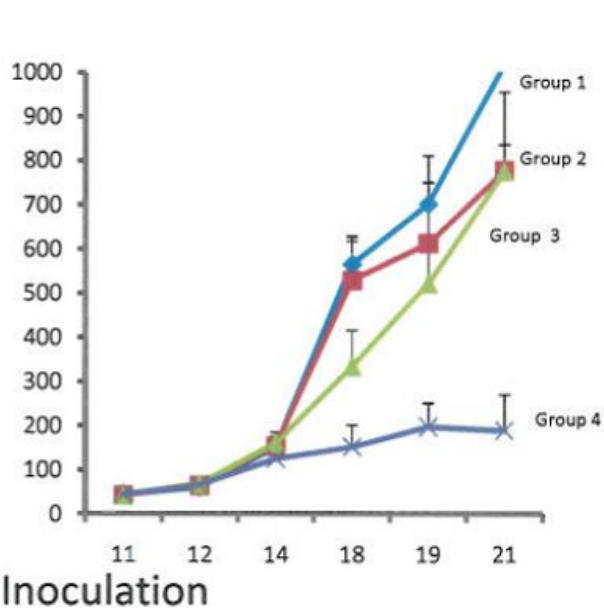


Systemic Tumor Response in B16 Melanoma Model

Treated Tumor on the Right Flank



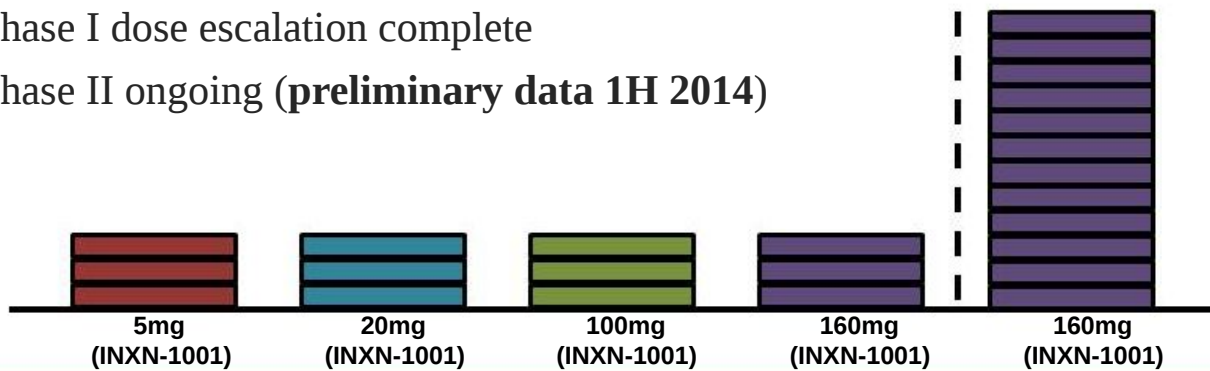
Untreated Tumor on the Left Flank



Group 1 untreated; Group 2 AL in food ~675 mg/m²/day; Group 3 Ad-RTS-mIL-12 1x10¹⁰ vp Days 12 & 19; Group 4 AL + Ad-RTS-mIL-12. Arrows = administration of Ad-RTS-mIL-12

A Phase I/II, Open Label Study of Ad-RTS-hIL-12 + AL in Subjects with Unresectable Stage III or IV Melanoma

- 3 + 3, single-arm design
 - 12 subjects in Phase I (dose escalation)
 - Up to 15 subjects in Phase 2 (expansion)
- Primary endpoint – Safety and tolerability of intratumoral injections of 1012 vp Ad-RTS-hIL-12 in combination with escalating doses of INXN-1001
- Secondary endpoint – Inform the selection of a dose of INXN-1001
- Phase I dose escalation complete
- Phase II ongoing (**preliminary data 1H 2014**)



Prominent Inflammatory Response Correlates with High levels of IFN- γ



- Initial increase in lesion size due to inflammatory response seen at Cycle 1 Day 16
- Lesion was undetectable at Cycle 2 Day 1
- Subject ultimately progressed and was taken off study



Summary of Immunological and Clinical Activity

- Clinical activity at higher dose cohorts (5 of 7, 71%)
 - Prominent inflammatory responses in injected and non-injected lesions
 - Decrease in size of injected and non-injected lesions
- Clinical activity at 100 mg and 160 mg doses coincided with the highest serum levels of IL-12 and IFN- γ
 - 4-fold median increases from baseline at peak levels compared with lower dose cohorts
- Dose-dependent increase in serum levels of IL-12 and IFN- γ
- Flow cytometric analyses of PBMCs revealed
 - 7-fold and 4-fold median increase from baseline at peak levels in absolute CD3+ and CD8+ T cell values, respectively, compared with lower dose cohorts

Summary of Safety

- Controlled expression of IL-12 limits systemic toxicity while inducing biological and clinical activity in a dose-dependent fashion
 - Toxicity reversible on stopping oral activator ligand
- The most common **related** TEAEs ($\geq 20\%$ of subjects):
 - Chills and Pyrexia (73% each), Nausea (67%), Fatigue (60%), Vomiting (33%), Anorexia (27%), Arthralgia and Diarrhea (20% each)
- Toxicity profile is consistent with the MOA of the drug
- No DLT identified
- One **unrelated** death secondary to septicemia

Advanced Breast Cancer

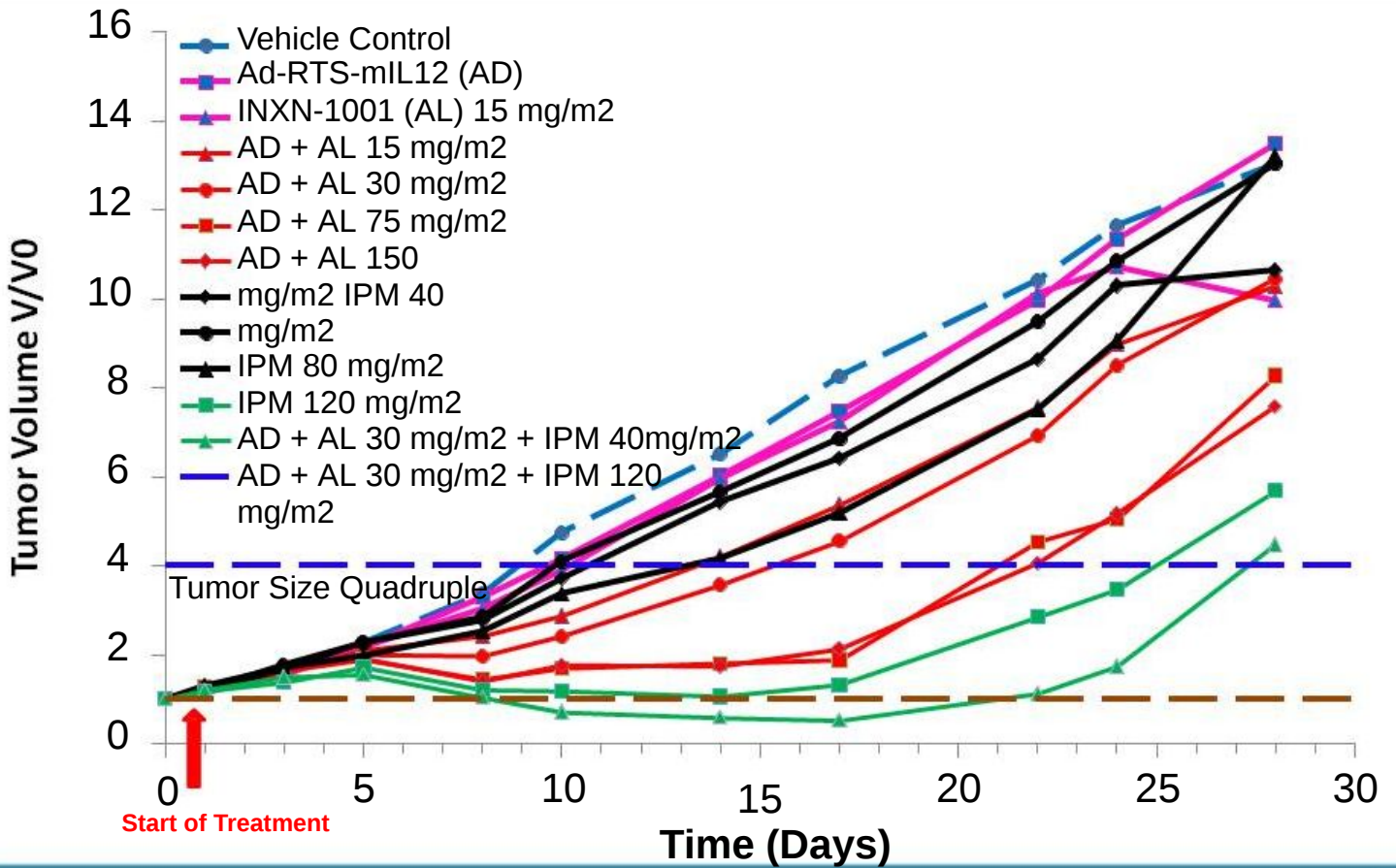
- **Preclinical**

- Intratumoral administration of Ad-RTS-mIL-12 (Ad) in 4T1 BALB/c mouse breast carcinoma model: dose-related decrease in tumor growth rate. (AACR 2013)
- Therapeutic strategy appears to be well tolerated

- **Phase 2**

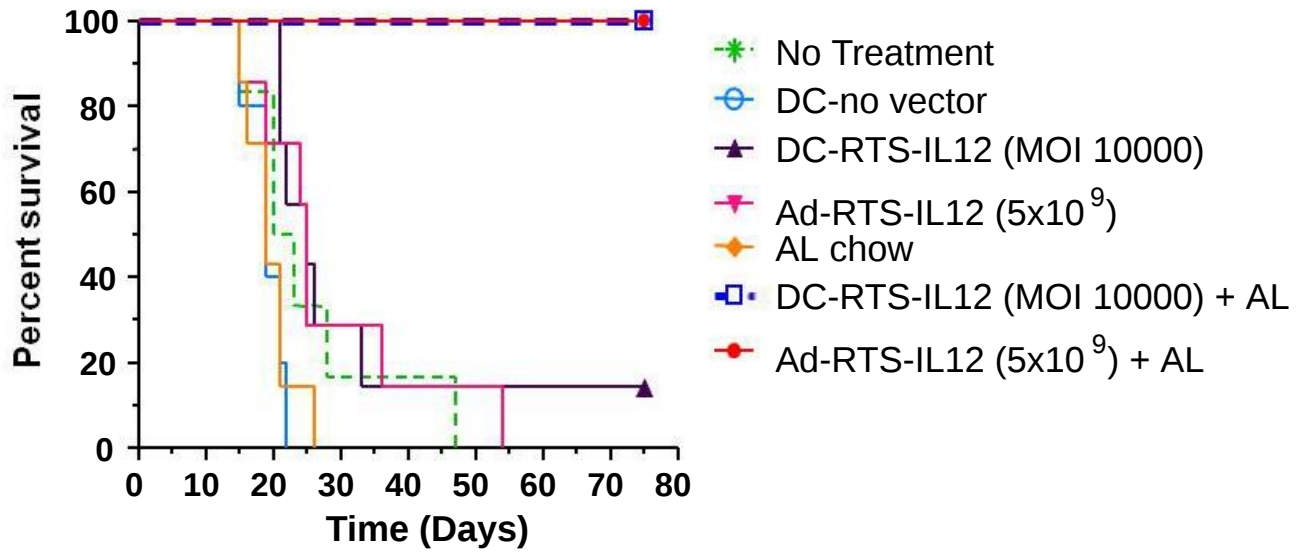
- Multi-center, randomized, open-label
- Ad-RTS IL-12 in combination w/palifosfamide
- Non-resectable, recurrent or metastatic breast cancer
- Enrolling up to 68 patients
- Early data expected year end 2013

Dose-dependent Anti-Tumor Activity of in Murine 4T1 (Breast Cancer) Model



Glioblastoma Multiforme: Promising Preclinical Activity

Kaplan Meier Survival in GL261 Orthotopic Syngeneic Mouse Glioma Model

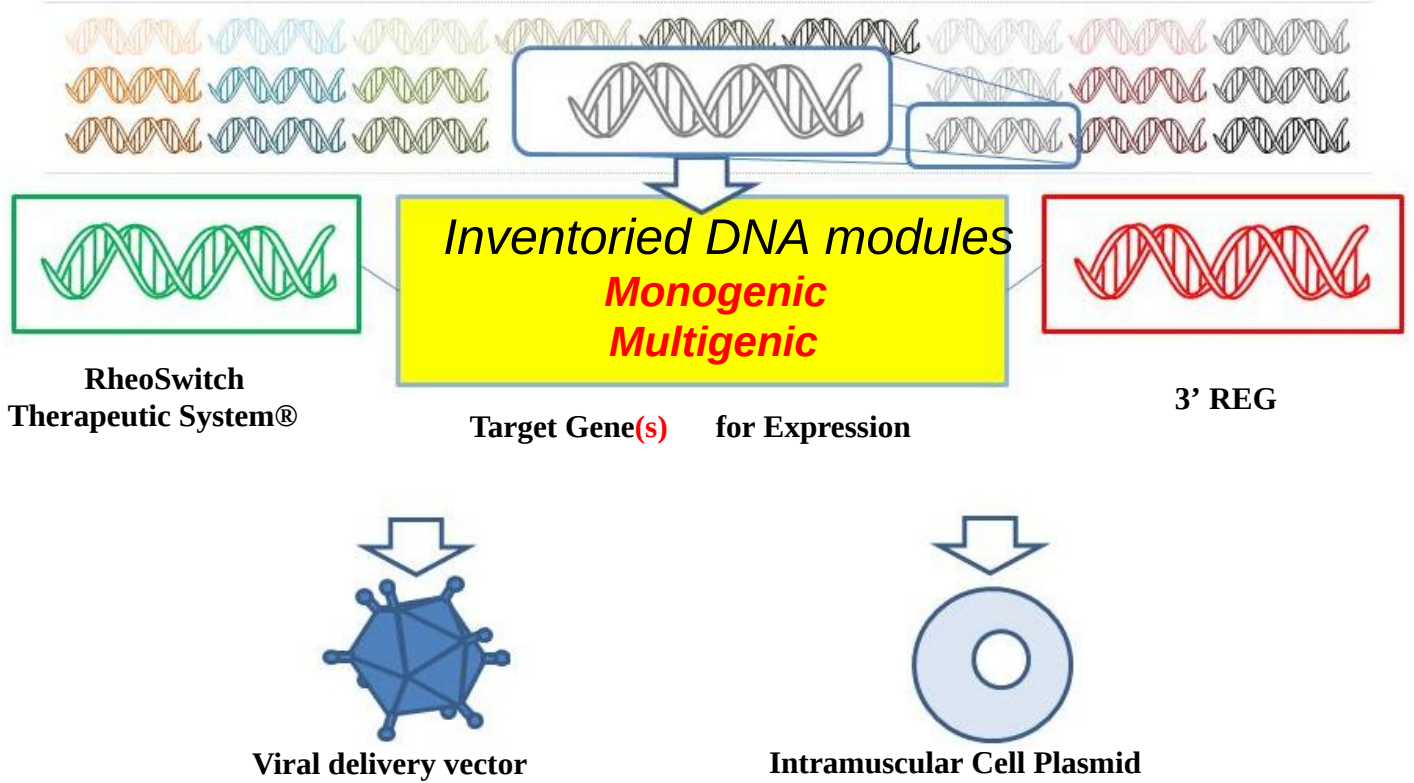


INXN-1001 dosing Day 4 to EOS at ~ 675 mg/m²/day in chow; DC -RTS-IL12 or Ad-RTS-IL12 on Day 5

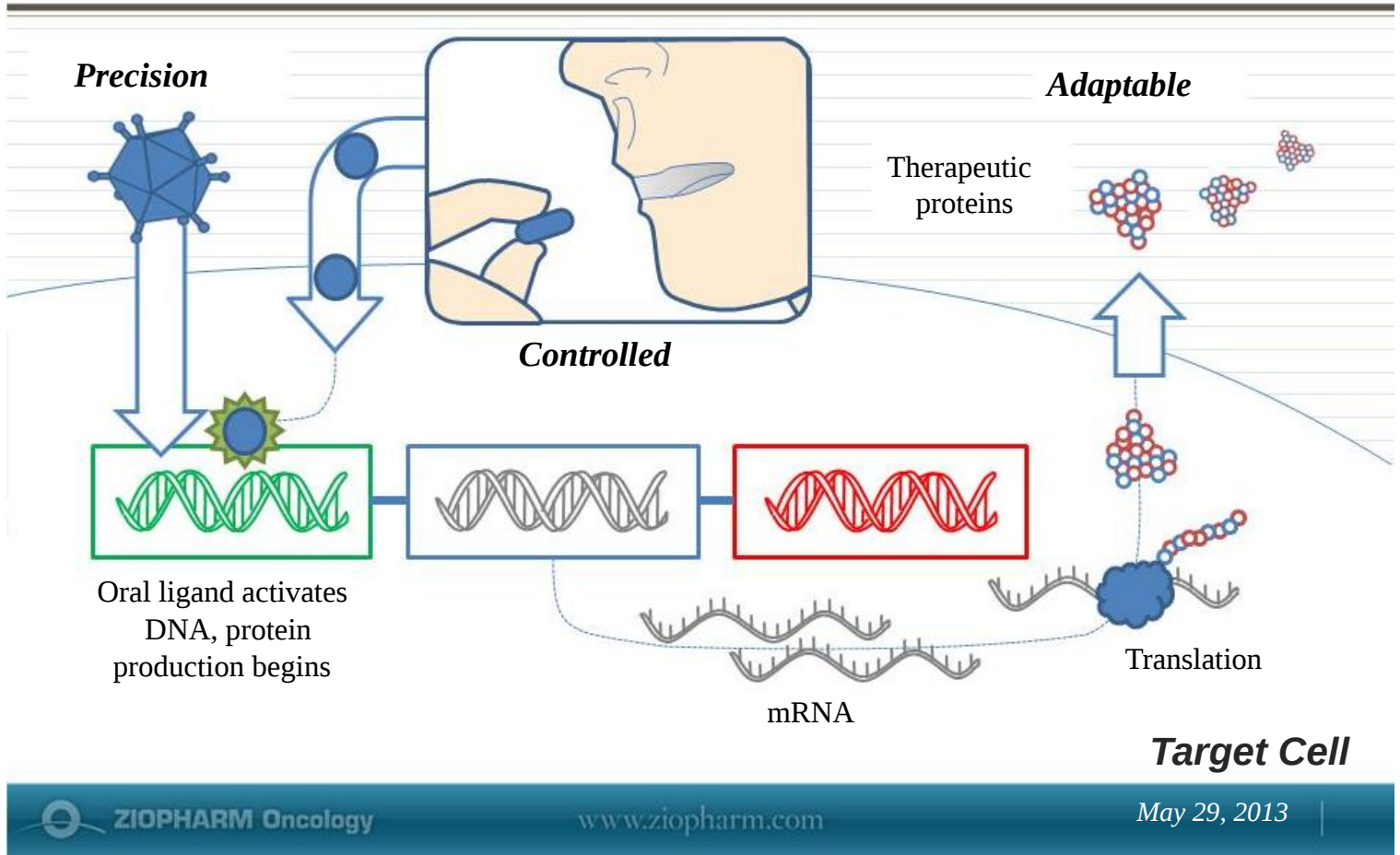
100 % survival observed with Ad-RTS-IL-12 + AL or DC-RTS-IL-12 + AL

Preclinical and Discovery Programs

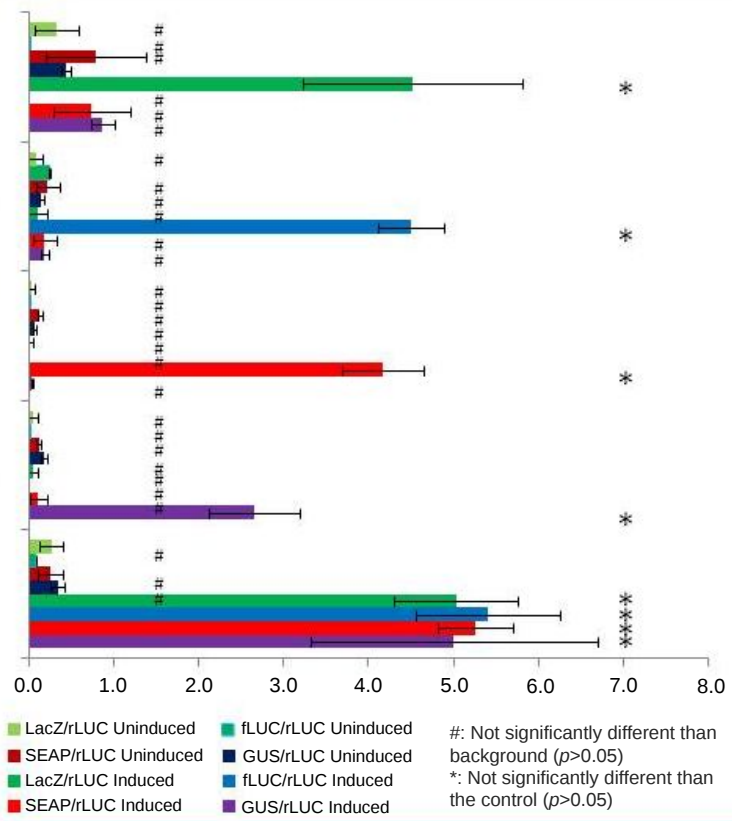
A Platform System for Rapidly Developing Controllable DNA Therapies



Using Natural Cell Biology to Regulate Proteins



Next Generation: Multigenic Approach



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

Small Molecule Programs

Small Molecule Programs

Palifosfamide

- Bi-functional DNA alkylating agent that has activity in multiple tumors by evading typical resistance pathways, less toxic and ease of administration
- Phase 3 soft tissue sarcoma program terminated, ongoing adaptive Phase 3 in small cell lung

Indibulin

- Novel oral tubulin binding agent; expected low toxicity, 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



Expected Milestones

Program	Milestone	Timing
2013		
IL-12	Melanoma preliminary Phase 2 data	4Q
	Breast cancer preliminary Phase 2 data	4Q
	GBM preclinical proof of concept	4Q
Multigenic platforms	Preclinical data	4Q
Immunotherapy Programs	Preclinical data	4Q
2014		
Palifosfamide	Interim SCLC data (MATISSE)	1H
IL-12	GBM Phase 1 / 2 study initiation	1H
	Melanoma Phase 2 data	1H
	Breast Phase 2 data	2H

Financial Highlights

- Primary shares outstanding: approximately 82.9M
- Cash: approximately \$55.7M @ 3/31/13
- Current cash resources expected to support operations into 1Q 2014

Conclusion

- Paradigm-shifting, synthetic biology technology for precise, controlled delivery of therapeutic proteins *in vivo*
- Engineered approach to product design allows us to rapidly develop new genetically-based treatments for cancer with multiple effectors
- Focused, disciplined and iterative approach to development
- Lead therapeutic Ad-RTS-IL-12 in Phase 2 melanoma and breast cancer for early validation of target and platform
- “Next-wave” of therapeutic approaches in research pipeline (antibody technology, protein-protein technology, immunotoxins, etc.)
- Well capitalized through data inflection points



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