

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 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): September 9, 2013

CELSION CORPORATION  
(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-15911  
(Commission File Number)

52-1256615  
(IRS Employer  
Identification No.)

997 Lenox Drive, Suite 100, Lawrenceville, New Jersey 08648  
(Address of Principal Executive Offices) (Zip Code)

(609) 896-9100  
(Registrant's telephone number, including area code)

N/A  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions ( see General Instruction A.2. below):

- 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 7.01 Regulation FD Disclosure.**

On September 9, 2013, Celsion Corporation. (the Company) made a presentation at the Rodman & Renshaw Global Investment Conference. A copy of the Company's presentation materials has been posted to the Company's website and is attached hereto as Exhibit 99.1.

*Limitation of Incorporation by Reference*

In accordance with General Instruction B.2. of Form 8-K, this information, including the Exhibit, is furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Current Report on Form 8-K will not be deemed an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

*Cautionary Statements*

This Current Report on Form 8-K and the presentations include "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including information about the Company's plans and expectations regarding its clinical studies and related FDA and regulatory matters.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Important factors that could impair the Company's business are disclosed in the "Risk Factors" contained in the Company's 2012 Annual Report on Form 10-K and on Form 10K/A and other periodic reports filed with the Securities and Exchange Commission. All forward-looking statements are expressly qualified in their entirety by such factors. We do not undertake any duty to update any forward-looking statement except as required by law.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Presentation

---

SIGNATURES

Pursuant to the requirements of the Exchange Act, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELSION CORPORATION

Dated:  
September 9, 2013

By: /s/ Jeffrey W. Church  
Jeffrey W. Church  
Senior Vice President and Chief Financial Officer

---

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	Presentation



## Rodman & Renshaw Global Investment Conference

September 9, 2013

**NASDAQ:** CLSN

**Presented by:**

Michael H. Tardugno

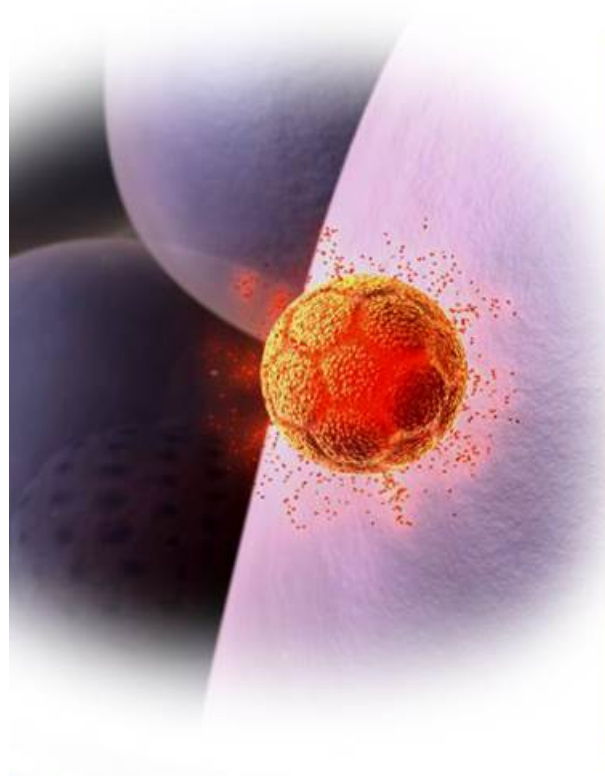
President and Chief Executive Officer

# Safe Harbor Statement

Except for historical information, the statements made in this presentation are forward-looking statements involving significant risks and uncertainties.

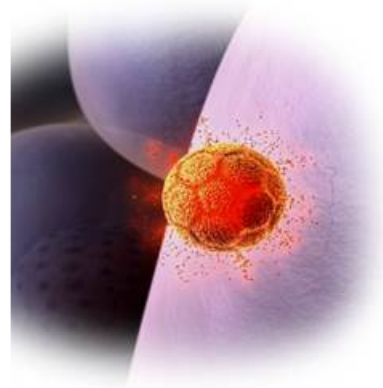
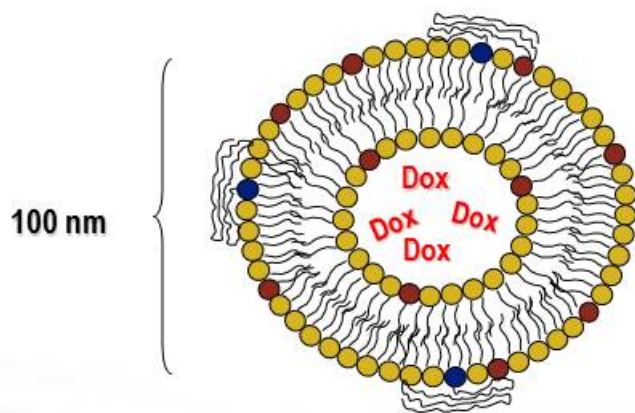
These risks and uncertainties, including those related to the future financial position and business strategy of the Company, are detailed in the Company's filings with the Securities and Exchange Commission.

# Celsion Investment Profile

- 
- Clinical stage oncology company focused on the development of heat activated tumor targeting liposome technology. 1<sup>st</sup> Drug ThermoDox
  - Results from Phase III trial "The HEAT Study" point to a large subgroup of patients showing meaningful benefit in overall survival
  - ThermoDox has potential to address multiple indications
  - Strong balance sheet ~ \$49M in cash

# ThermoDox's Elegant Design

- Transition temperature of 39.5 deg C releases the encapsulated Doxorubicin without compromising healthy tissue
- Half-life and nano-particle size provide adequate systemic circulation and vascular leakage allowing tumor biology to concentrate ThermoDox at the target
- FDA cleared heat inducing medical devices warm the target tumor initiating rapid drug release in the local vasculature



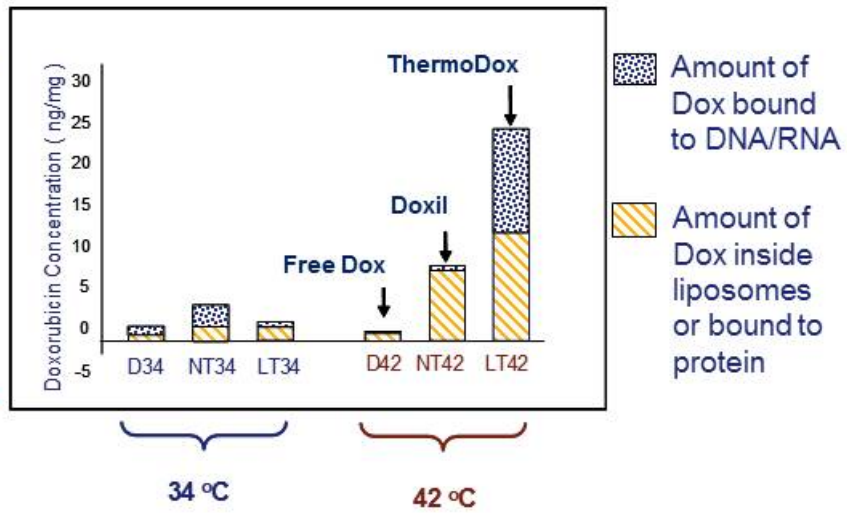
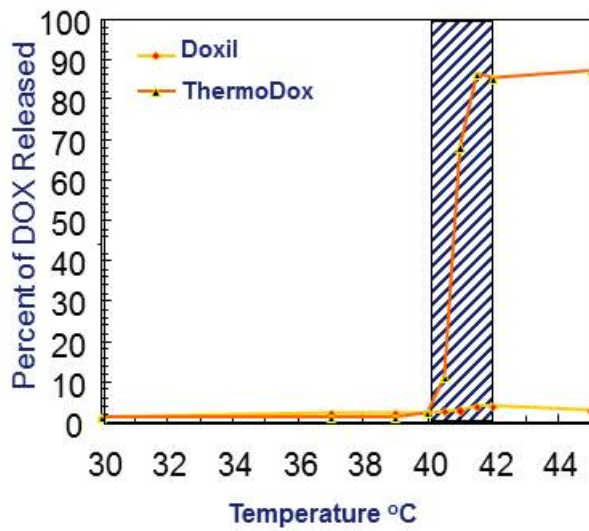


# ThermoDox's Mechanism

## Preclinical Evidence

Drug Release Occurs at Clinically Achievable Temperature, 39-42°C

1 hour at 42°C, heat-sensitive dosage form delivered most drug to tumor

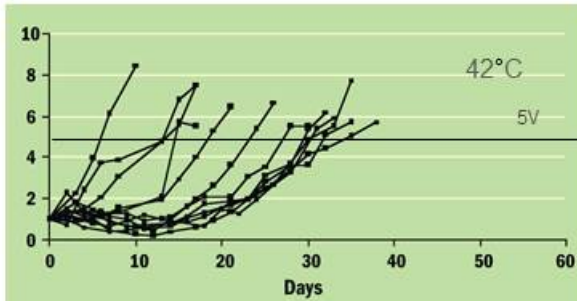


# ThermoDox's Mechanism

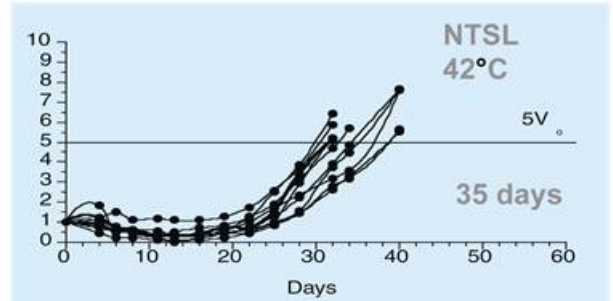
## Preclinical Evidence

### Nude Mouse - Squamous Cell Tumor Xenograft Model

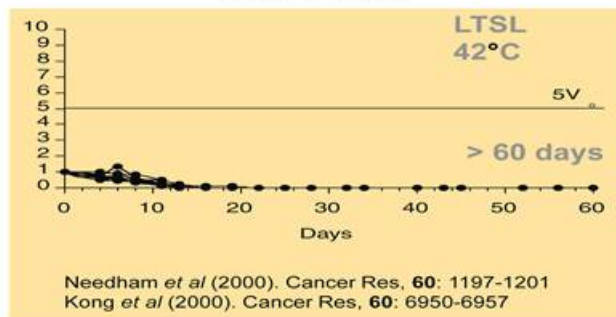
#### Free Doxorubicin



#### Doxil®



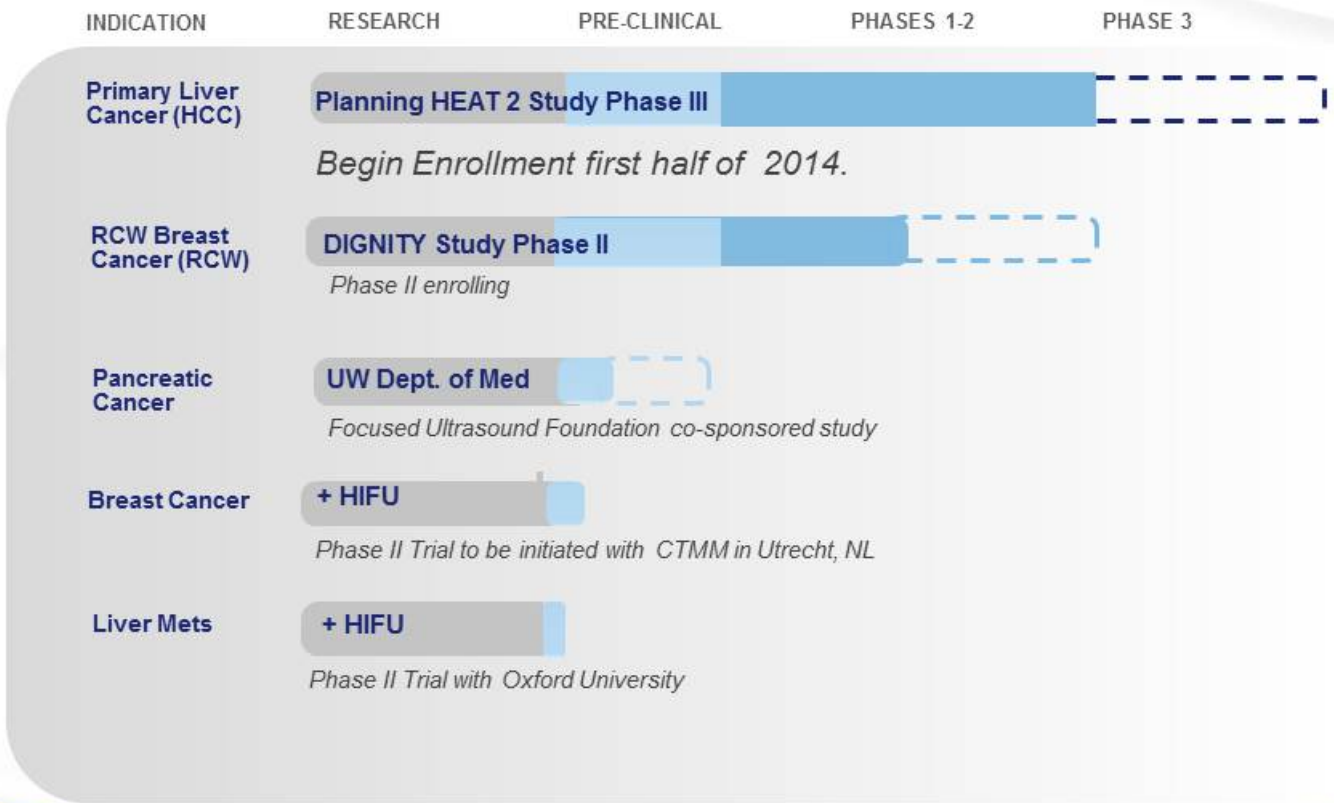
#### ThermoDox®



**All tumors regressed in ThermoDox group**

# ThermoDox Clinical Program

## Evaluating Multiple Oncology Indications



# Hepatocellular Carcinoma

## Large and Deadly Global Cancer

### 5th most prevalent

- 750,000 annual incidence worldwide; growing over 5% per year
- By 2020, expected to be the #1 cancer, surpassing lung cancer
- China has 50% of new cases, 75% in Asia
- Age-adjusted HCC incidence rates tripled in U.S. between 1975 and 2005

### 4th highest mortality

- 5-year survival rate less than 10%
- Median survival from time of diagnosis is generally 30 months
- Cure, usually through surgery, is possible in fewer than 20% of patients

### Local therapies include:

- RFA, TACE, ethanol injection and radiation therapy
- RFA is the dominant treatment for non-resectable liver cancers with average local recurrence rate of 50%+/- for lesions >3cm
- ThermoDox + RFA addresses limitations of current standard of care by "*Expanding the Treatment Zone*"

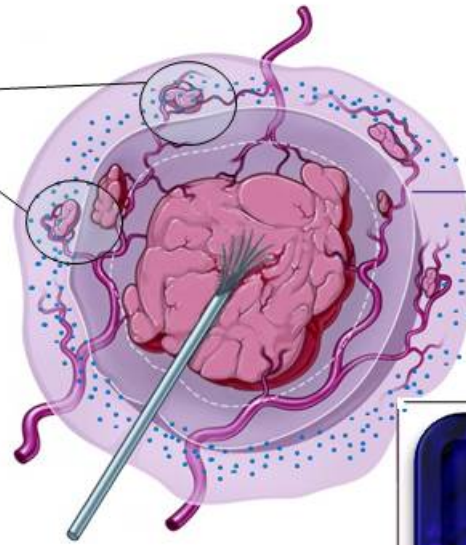
# RF Liver Ablation + ThermoDox

Expanding the Treatment Zone Addresses RFA Limitations

RFA misses micro-metastases outside ablation zone

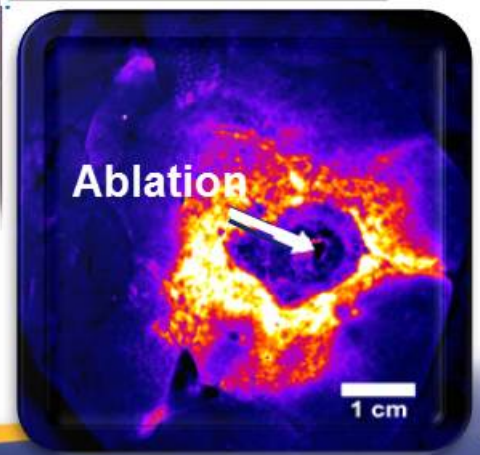
## ThermoDox + RFA:

- Infuse ThermoDox ~15 minutes prior to RFA
- Drug concentrates in the "Thermal Zone"
- Ablation releases doxorubicin in "Thermal Zone" expanding treatment area and destroying micro-metastases



ThermoDox  
Ablation Zone  
Thermal Zone

RFA Electrode



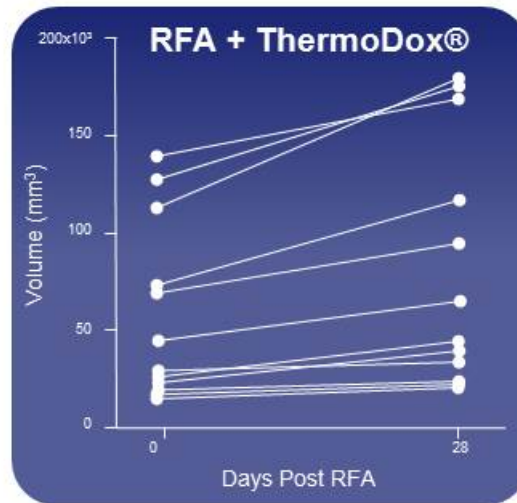
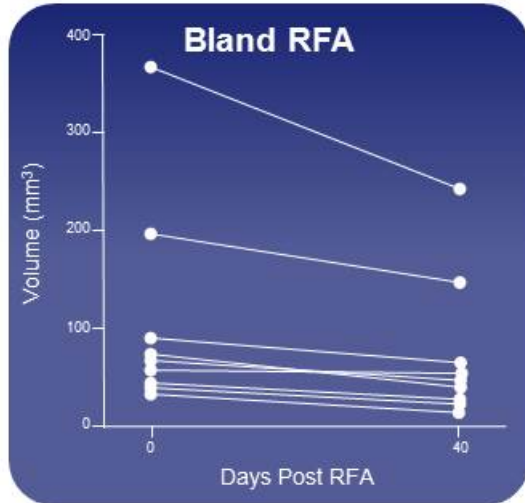
Ablation

1 cm

# Phase I Liver Cancer Results

Highly Suggestive of Clinical Activity

- 2 Clinical Sites: NCI (US) and Queen Mary Hospital (HK)
- Single dose treatment; 50mg/m<sup>2</sup> MTD established
- No unanticipated SAE or AE experienced



Pre-treatment



11 weeks post-treatment



20 weeks post-treatment



**Treatment Zone Increases**

## HEAT 1 Study did not meet PFS Endpoint

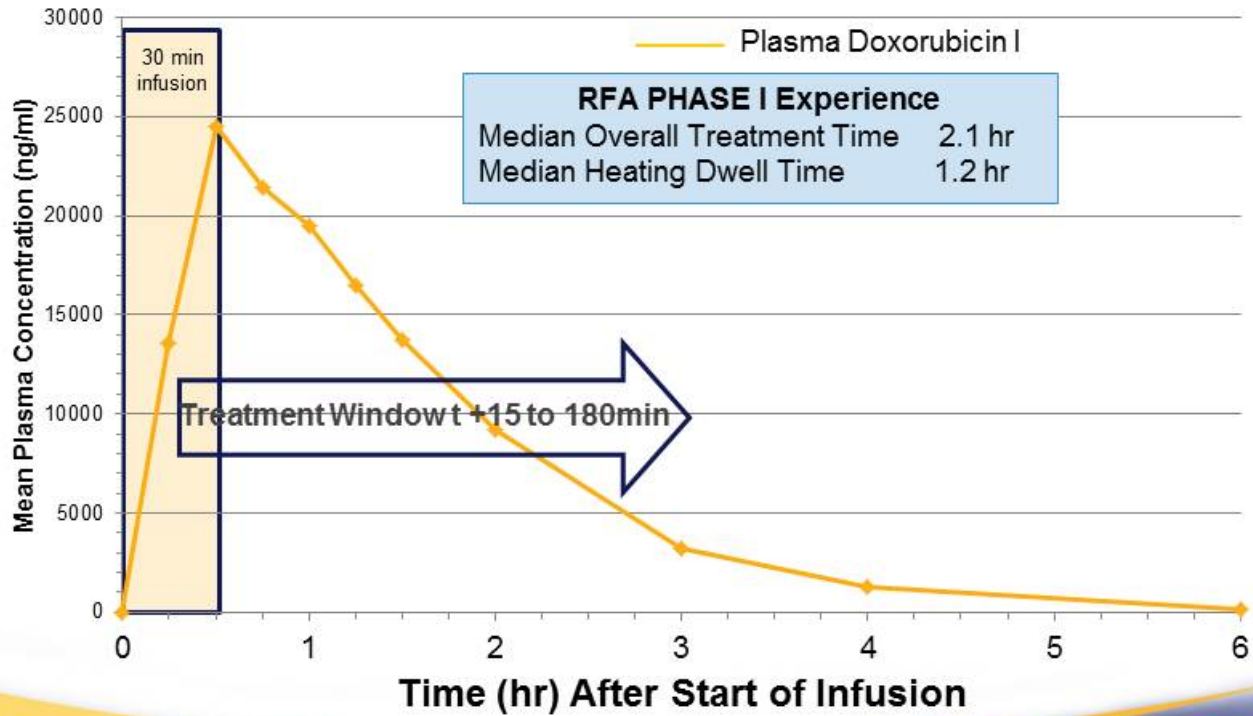
Patients are being followed to determine the OS benefit per Protocol



- Study did not meet Primary Endpoint PFS: 14.0 mos. vs. 13.9 mos.
- Patients with smaller lesions (< 5 cm) showed ~20% PFS benefit
- Meaningful Sub-Group, ~300 Identified
  - Patients with single lesions
  - RFA dwell time > 45 minutes
  - OS improvement of > 50%
- Heat 2 Study planned pending Regulatory Review
  - Data Analysis, conformational Preclinical Studies, Advisory Committee input

# HEAT 1 Study Treatment Window

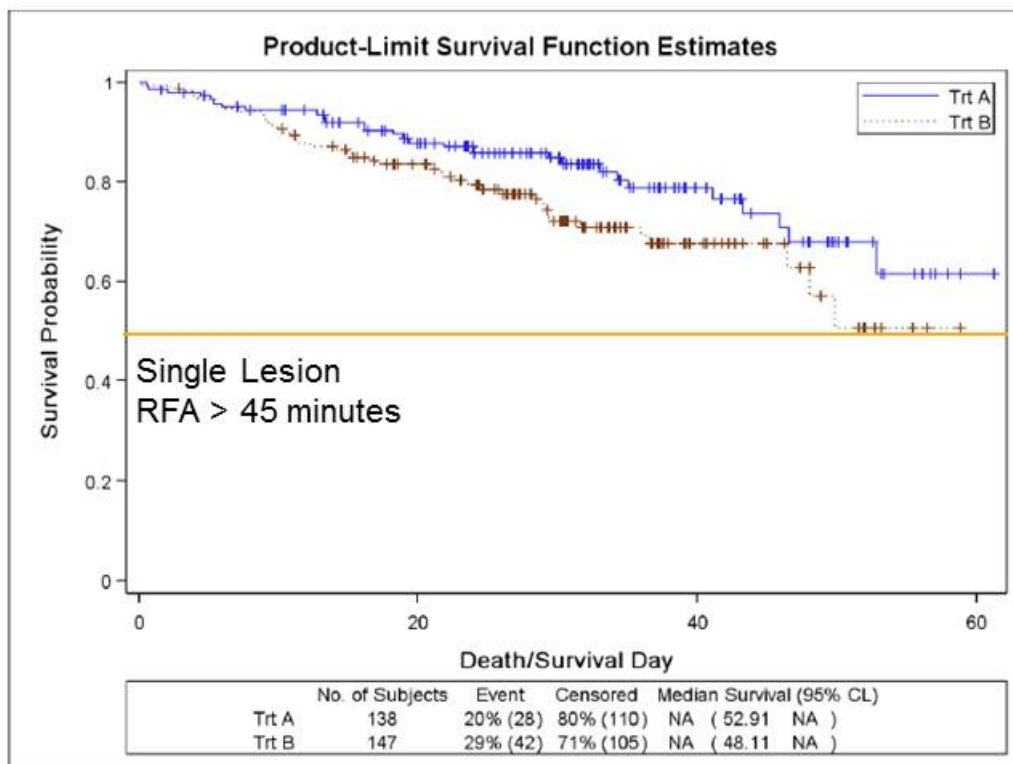
- Ablation time and strategy were not mandated in HEAT Study
- Variability exists with ablation cycles and treatment time by lesion size, location, and local practice





# RFA Duration May Have Marked Effect

Projection for OS improves >50%



As of 6/30/2013

HR = 0.623

*P-value* = 0.0584

## RFA Duration May Have Marked Effect

Projection for OS improves >50%

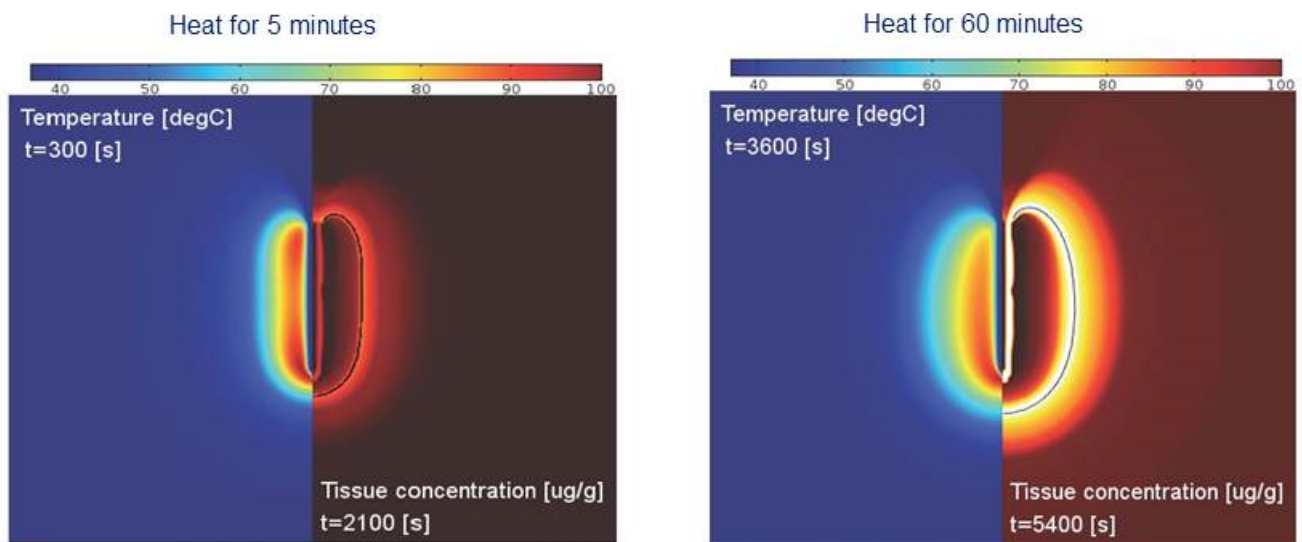
		# of Pts	Deaths		HR
< 45 mins	RFA + TDox	96	29	30%	1.139
	RFA Only	71	27	38%	
		<u>167</u>	<u>56</u>		
> 45< 90 mins	RFA + TDox	76	14	18%	0.585
	RFA Only	105	27	26%	
		<u>181</u>	<u>41</u>		
> 90 mins	RFA + TDox	62	14	23%	0.584
	RFA Only	42	15	36%	
		<u>104</u>	<u>29</u>		

> 45 mins	RFA + TDox	138	28	20%	0.623	p = 0.058
	RFA Only	147	42	29%		
		<u>285</u>	<u>70</u>			

# ThermoDox + RFA HCC Thesis

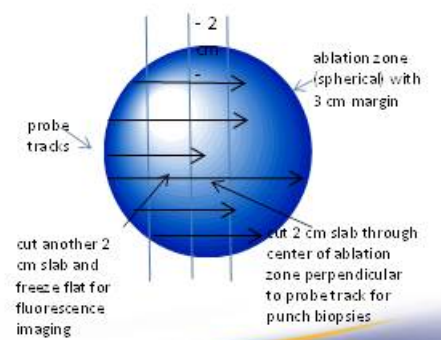
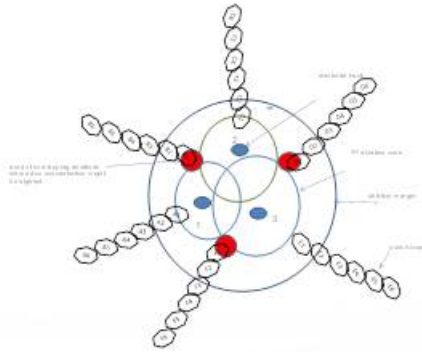
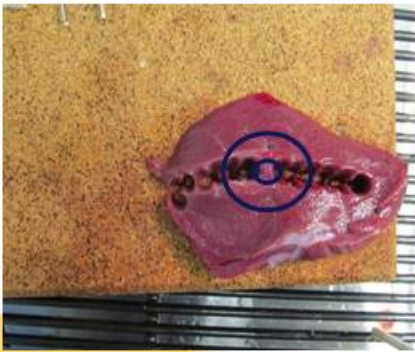
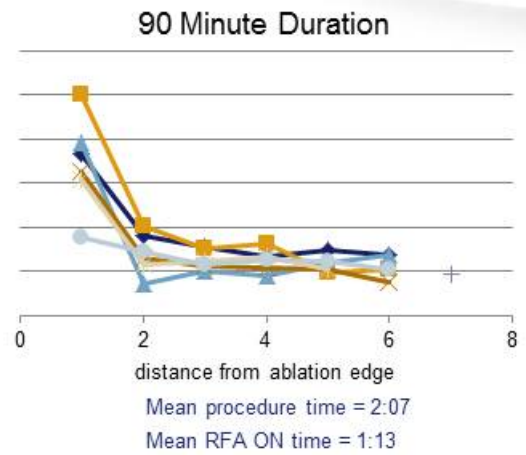
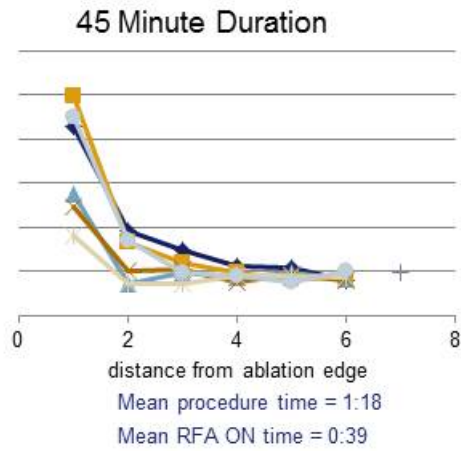
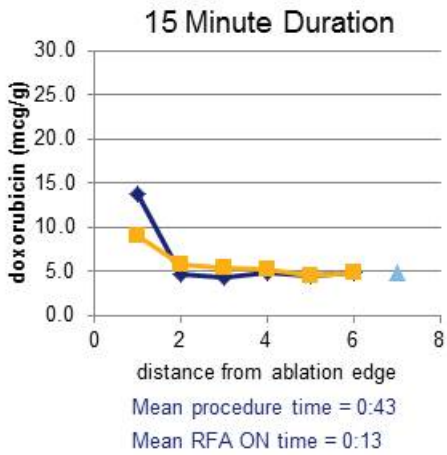
Under-Treating When Heat < 45 min

Recent simulation studies show that longer heating time is required in order to achieve increased tissue concentrations of doxorubicin



# Healthy Swine RFA Dwell Time Study

Preliminary data supportive of clinical hypothesis



## Findings From Post-Hoc Analysis

- A strong relationship exists between heating duration and clinical outcome. In general, the longer the RFA time the better the outcome.
  - ThermoDox appears to markedly enhance this effect
- Hypothesis: High local tissue concentration of ThermoDox prevents HCC recurrence
  - Effective thermal dosing is dependent on tumor burden
  - Minimum range appears to be 45-90 minutes dependent on size and location
- Suboptimal dwell time and/or time of thermal dosing results in inferior outcome for ThermoDox patients

# HEAT 2 Study

Preliminary Design requires a well defined RFA procedure

<b>Primary Endpoint:</b>	Progression Free Survival
<b>Secondary Endpoints:</b>	Overall Survival, Time to Local Recurrence, Time to Definite Worsening and Safety



# ThermoDox + Hyperthermia RCW Breast Cancer



- 16 pts, all show clinical activity
- At 30 mg/m<sup>2</sup>, 6/6 subjects showed a clinical response, 2 CR

Limited Treatment Options



Complete Response



## DIGNITY Study

RCW study of ThermoDox<sup>®</sup>  
and microwave hyperthermia

Overall Response Rate (ORR) of 48%

**Ph I** 11 Pts. 50 mg/m<sup>2</sup> dose established

Enrollment Initiated in 2013 Open Label

**Ph II** Durable Complete Local Response Rate; Evaluate Site Comparability

### Eligibility:

Mastectomy Patients who have recurrence on the chest wall who have had a and prior treatment

### Enrollment:

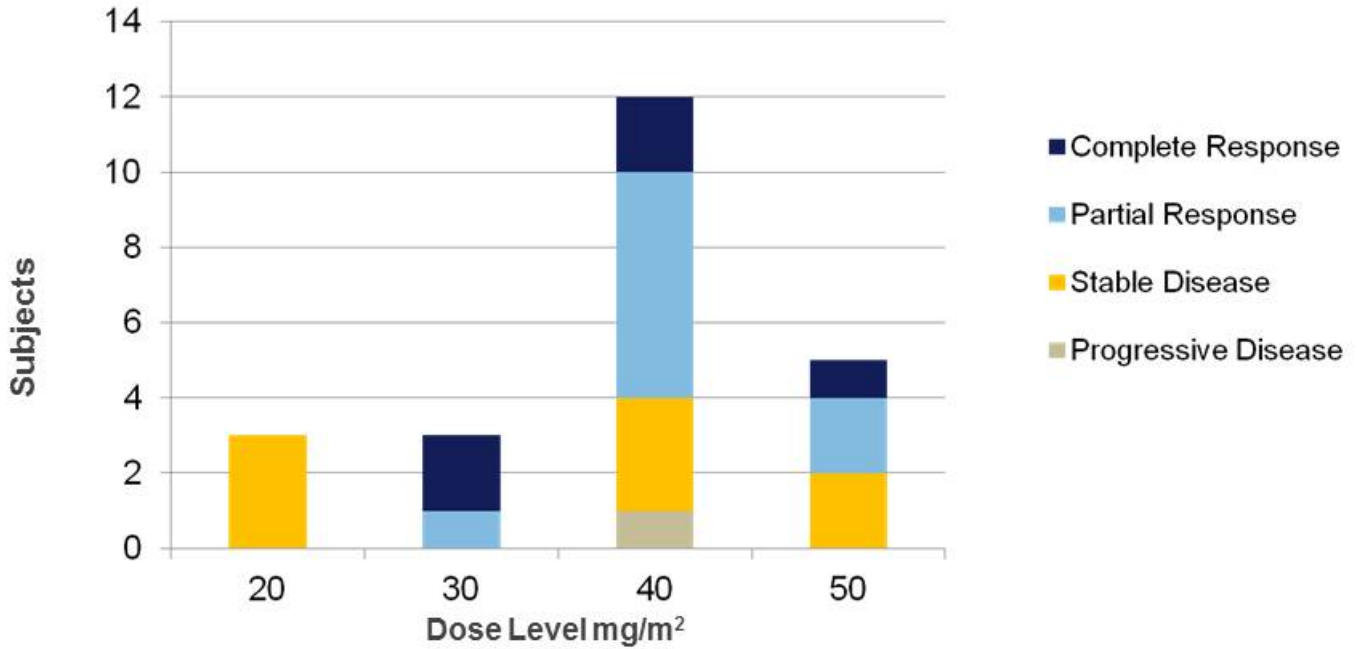
40 patients, 5 Institutions

Individual patient results beginning Q2 2014

# ThermoDox + Hyperthermia

## RCW Breast Cancer Phase I Studies

Combined Local Response Rate 48.3%



22 of 23 (29) evaluable, per protocol, subjects demonstrate CR, PR or SD within the local treatment field



# ThermoDox + MRI guided HIFU

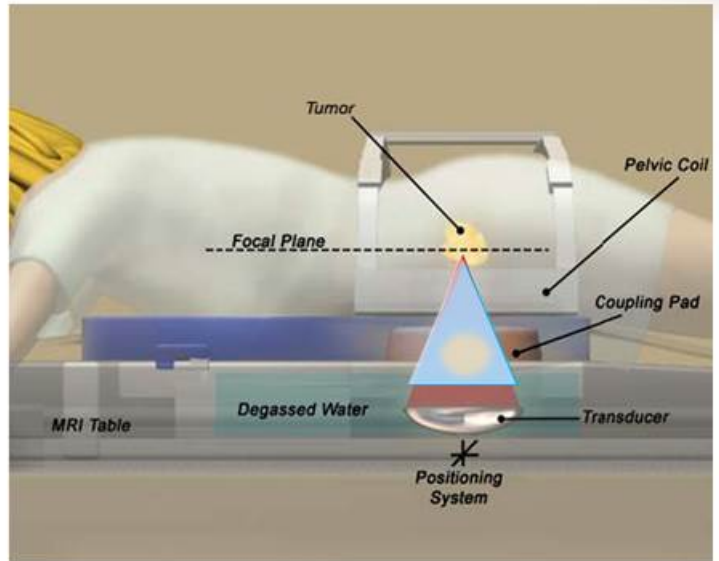
Broadens Reach to Indications with Significant Need

## Collaboration with University of Oxford

- Phase II ThermoDox + HIFU for metastatic liver cancer - Significant unmet need
- Pre-Clinical studies complete

## Pre-Clinical Studies

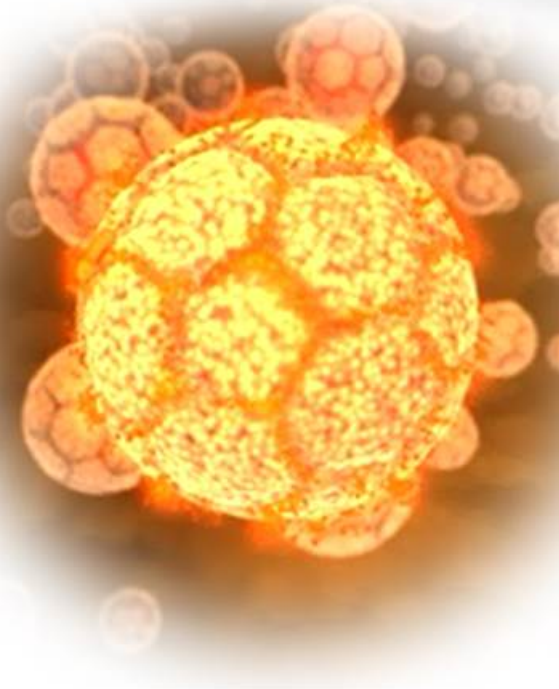
- University of Washington with support from the Focused Ultrasound Foundation - ThermoDox + HIFU for pancreatic cancer
- University of Utrecht (Netherlands) under a \$10 million European Cooperative Grant for MR-guided HIFU + ThermoDox for the treatment of various cancers



# Celsion Investment Profile

## Patent and Regulatory Protection

- Exclusive world-wide rights from Duke University Patent to 2019
- Additional U.S Patent extension expected under Hatch-Waxman
- New method patents issued in China, Taiwan, South Korea and Japan extending into 2026
- Orphan Drug Designation in U.S. and Europe provides 7 and 10 year exclusivity



# Next Steps and Milestones

## **Q3 - 2013**

Complete HEAT Study 1 Analysis

- Present Post Hoc Findings (WCIO, ECIO, ILCA)

Confirm hypothesis through modeling & animal studies

- Proposed HEAT 2 Study Design
- Steering (Advisory) Committee to finalize HEAT 2 Study Design

## **Q4 – 2013**

Review plans and protocol with regulatory agencies

- Seek agreement for enriched population, single trial for approval
- FDA, EMA, CFDA

## **1H – 2014**

Begin HEAT 2 Study Enrollment

- High performance sites from HEAT 1 Study
- Concentrations in China; Expand European footprint

Initial reporting from DIGNITY Study

# Financial Summary



<b>Cash &amp; Investments @ 6/30/13</b>	\$49 M
<b>Est. Cash Usage</b>	~ \$1 M/mo.
<b>Common shares outstanding</b>	61.2 M
<b>52-week PPS Range</b>	\$0.77 - \$9.44
<b>Market Cap</b>	\$75 M
<b>Average Daily Trading Volume</b>	> 2.5 M



## Corporate Information

**Celsion Corporation**

997 Lenox Drive

Suite 100

Lawrenceville, NJ 08648

P 609-896-9100

F 609-896-2200

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

**NASDAQ:** CLSN