



## 24<sup>th</sup> Annual ROTH Conference

March 11 – 14, 2012

**NASDAQ:** CLSN

**Presented by:**

Jeffrey W. Church

Sr. Vice President, Corporate Strategy &

Investor Relations

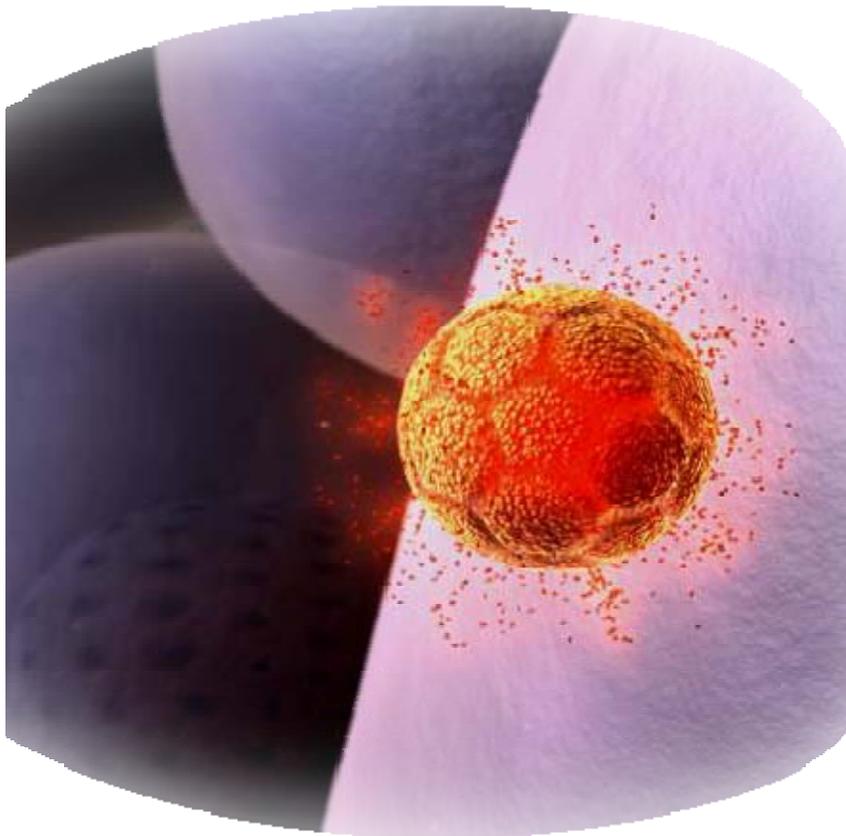
# Safe Harbor Statement



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



Oncology focused development stage company addressing largest unmet need in cancer - Hepatocellular Carcinoma (HCC)

Platform technology provides highly effective, targeted delivery of approved chemotherapeutics

ThermoDox<sup>®</sup> is in a Phase III pivotal trial (“HEAT Study”) with data by year-end

Strong Balance Sheet with cash sufficient to secure top line data

Represents billion dollar market opportunity

# Phase III HEAT Study



## Special Protocol Assessment for US

- 600 patient enrollment target reached; continuing to 700 (r 1:1)
- 380 PFS events Primary Endpoint
- 372 deaths for Overall Survival (secondary endpoint read out)

## HEAT Study Protocol accepted by EMA

- Acceptable for centralized filing of Marketing Authorization Application
- PFS alone may be sufficient for unconditional approval
- Preclinical and manufacturing strategy supported

# Phase III HEAT Study:

## RFA + ThermoDox for HCC

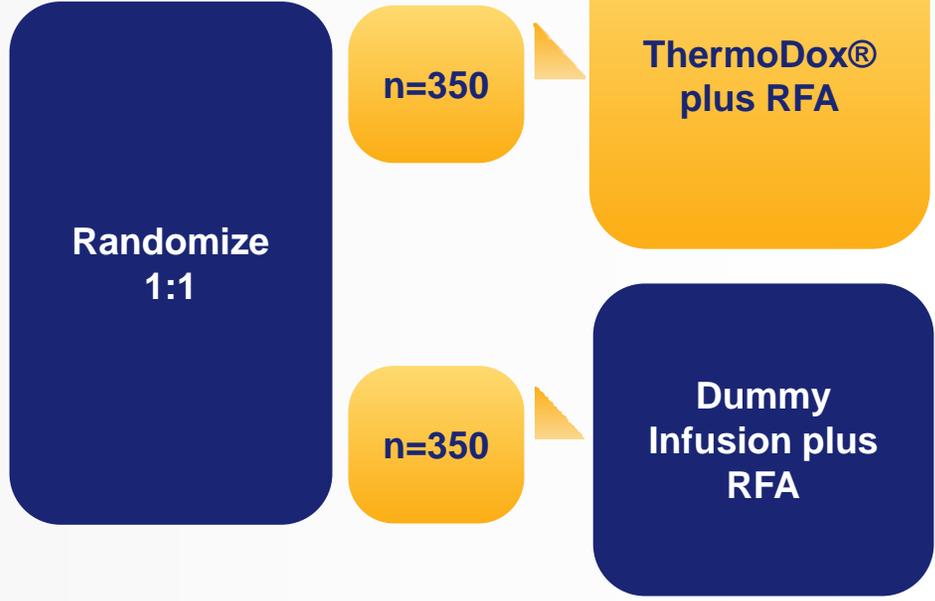
<b>Primary Endpoint:</b>	Progression Free Survival
<b>Secondary Endpoints:</b>	Overall Survival, Time to Local Recurrence, Time to Definite Worsening, and Safety

### General Eligibility:

- Non-resectable HCC
- No more than 4 lesions
- At least 1 lesion > 3cm and none > 7cm
- No previous treatment
- Child-Pugh A or B

### Stratification:

- Lesion size: 3-5 and >5-7
- RFA technique:
  - Open surgical
  - Laparoscopic
  - Percutaneous



# Celsion Investment Profile

## Fastest Path Regulatory Strategy



Unmet  
Need

**#1 unaddressed Cancer**

HBV & HCV put millions at risk, globally

**NIH "Priority Trial"**

CDC "growing global healthcare issue"

Accelerated  
Trial

**Agreed to SPA**

Supported by 10 regulatory agencies

**Accelerated endpoint**

Progression Free Survival (PFS)

Accelerated  
NDA

**Fast track granted**

Rolling NDA begins in 2012

**Priority review**

6 months PDUFA

**505(b)(2) eligible for U.S.**

Pre-clinical studies sufficient to support NDA

**EU, China, Taiwan, S. Korea**

Phase III trial as a stand alone for filing

# Celsion Investment Profile

Interim Analysis by the DMC Supports Continuation



**HEAT Study**

Hepatocellular Carcinoma Study  
of RFA and ThermoDox<sup>®</sup>

**Unanimous Recommendation to  
Complete the Study after Interim Efficacy  
Review by DMC (Nov 2011)**

**In Full Alignment Following Discussions  
with FDA (Q1-2012)**

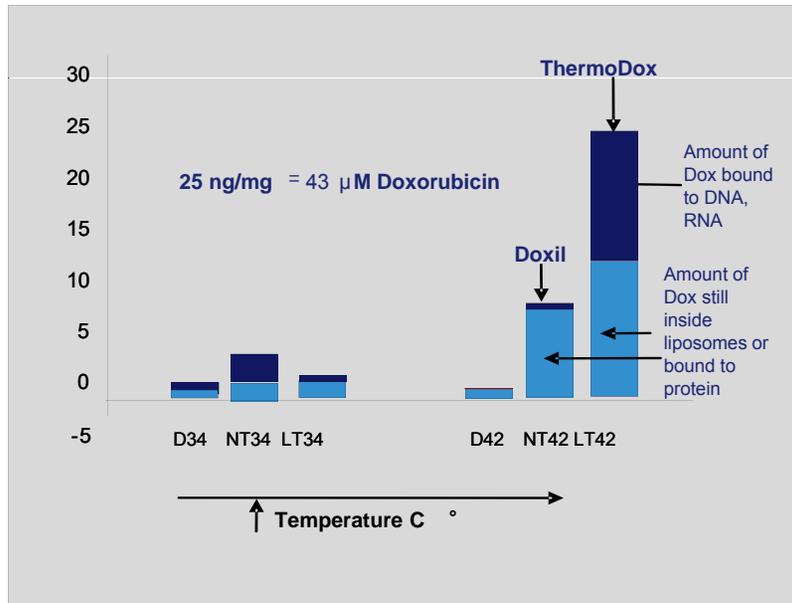
- No additional interim efficacy analyses
- Special Protocol Assessment and Statistical Plan is fully powered at 380 PFS events

**Top Line Data projected for year end  
2012**

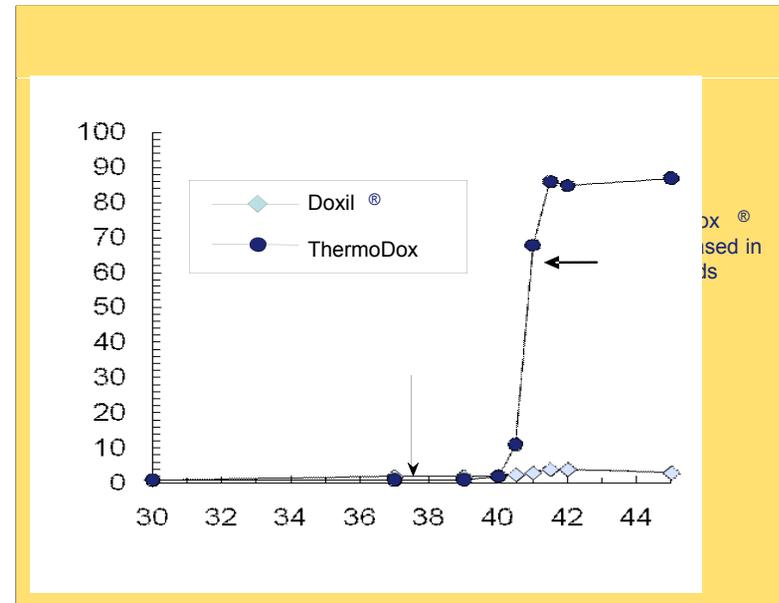
# ThermoDox Pre-Clinical Studies

## Chemotherapy Directly to Tumor with Superior Activity

**IN VITRO** After 1 hour at 42°C, heat-sensitive formulation delivered most drug to tumor



**IN VITRO** Drug release occurs at clinically achievable temperature



# Hepatocellular Carcinoma (HCC)

## 1st Indication



### 5th most prevalent cancer globally

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

### 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

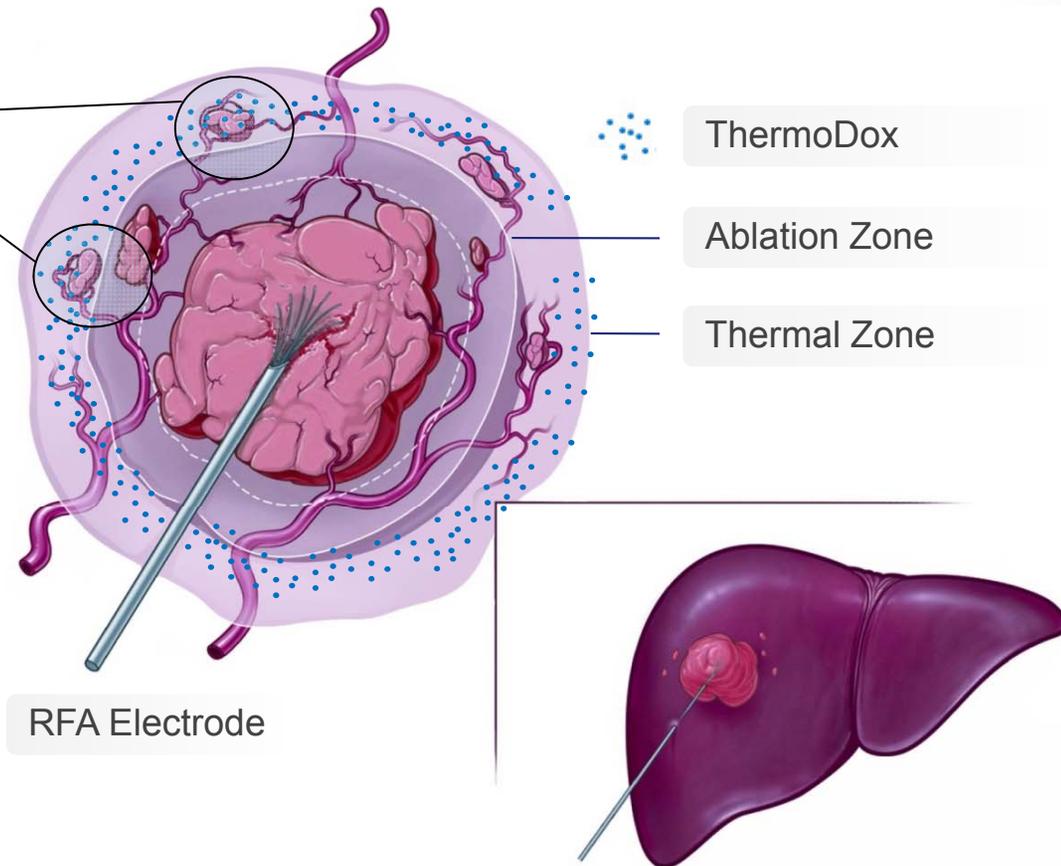
# RF Liver Ablation + ThermoDox

Expanding the Treatment Zone Addresses RFA Limitations

RFA misses micro-metastases outside ablation zone

## ThermoDox + RFA:

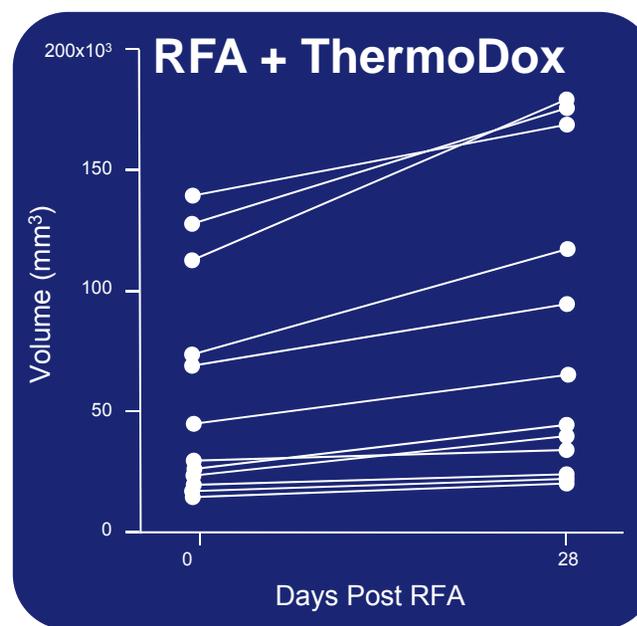
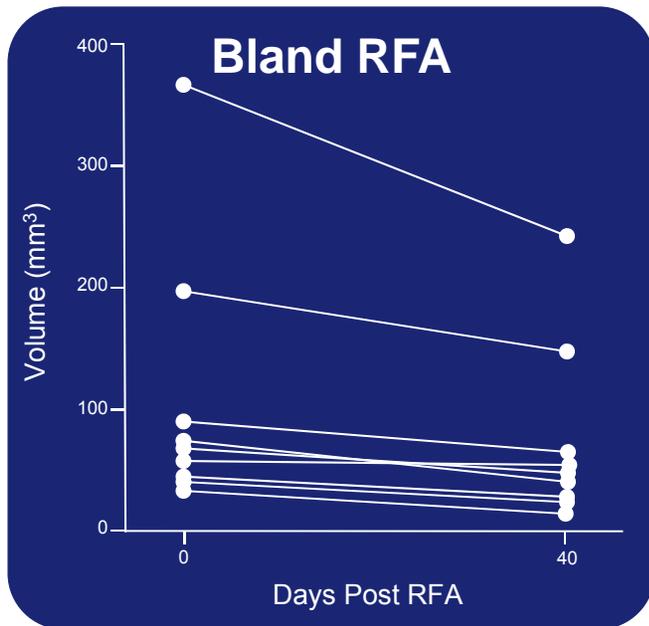
- Infuse ThermoDox ~15 minutes prior to RFA
- Drug concentrates in the "Thermal Zone"
- Ablation releases doxorubicin in "Thermal Zone" expanding treatment area and destroying micro-metastases



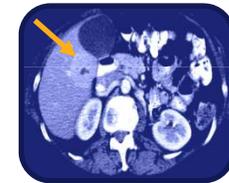
# Phase I Liver Cancer Results

Highly Suggestive of Clinical Activity

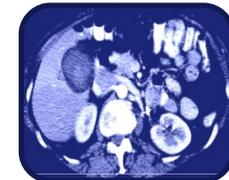
- 2 Clinical Sites: NCI (US) and Queen Mary Hospital (HK)
- Single dose treatment; 50mg/m<sup>2</sup> MTD established
- No unanticipated SAE or AE experienced



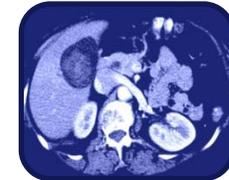
Pre-treatment



11 weeks post-treatment



20 weeks post-treatment

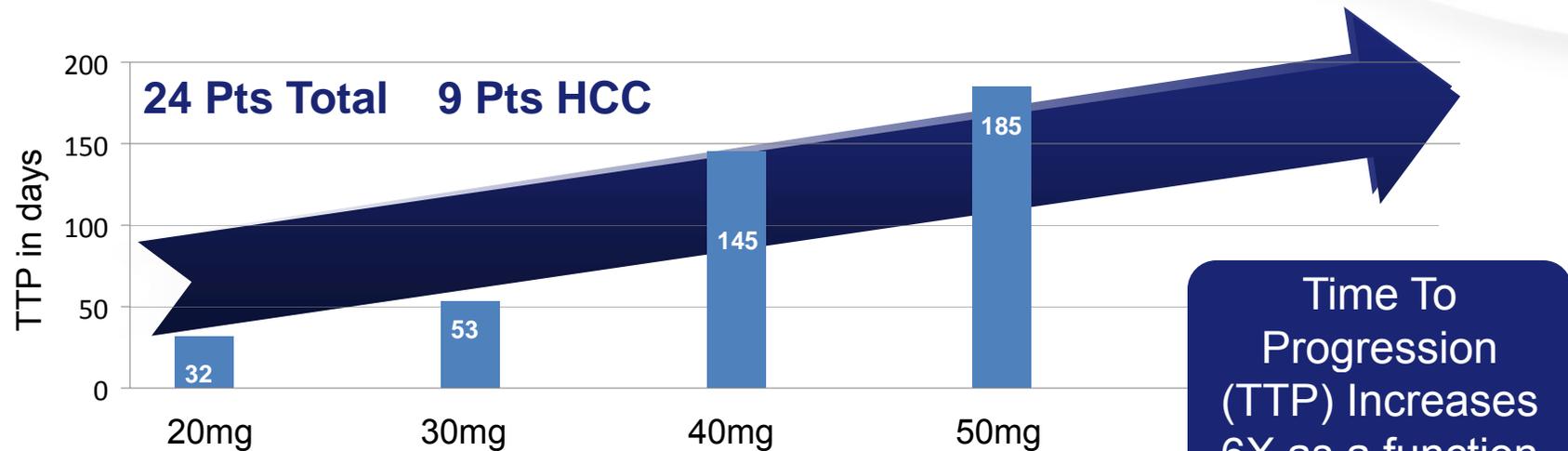


**Treatment Zone Increases**

Evidence of clinical activity presented by Dr. B. Wood, NCI at the 2007 ASCO-GI Conference.

# Phase I Liver Cancer Results

Dose Response Correlation Supports Phase III PFS Endpoint



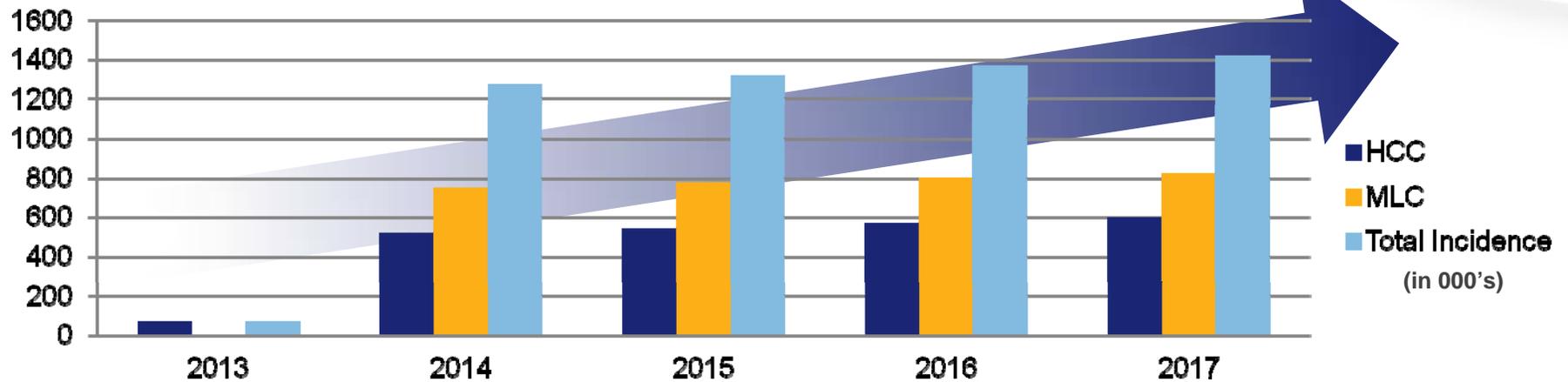
- 185 days to progression at the MTD, 50mg/m<sup>2</sup> a 6 fold improvement over the baseline, 20mg/m<sup>2</sup> <sup>(1)</sup>
- Dose uniquely shows statistical significance, p=0.038 <sup>(2)</sup>
- In the HCC subgroup, TTP more than doubles at therapeutic doses, 50 and 60mg/m<sup>2</sup>

(1) Phase I data presented at IHPBA Conference, Mumbai, India, February, 2008, Dr. R Poon

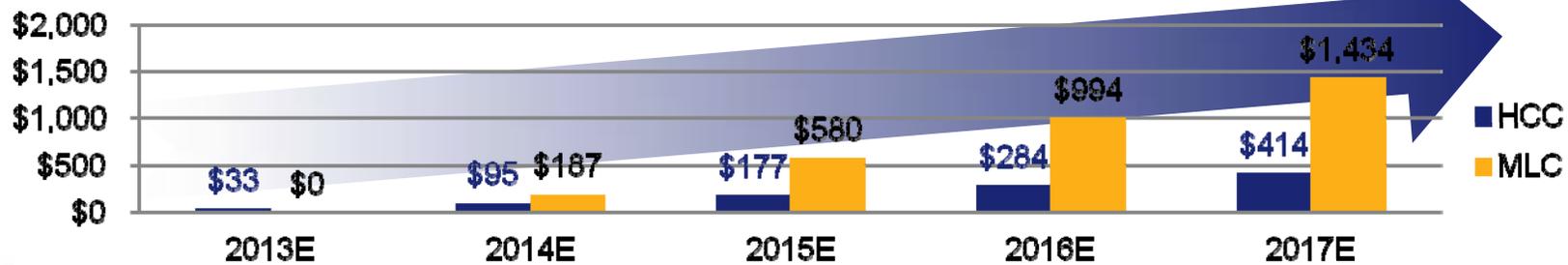
(2) Manuscript: Poon, Borys, Expert Opinion, Pharmcother, 2009

# Studied Liver Cancers Revenue Potential

Addressable Incidence Growing +5% Annually WW

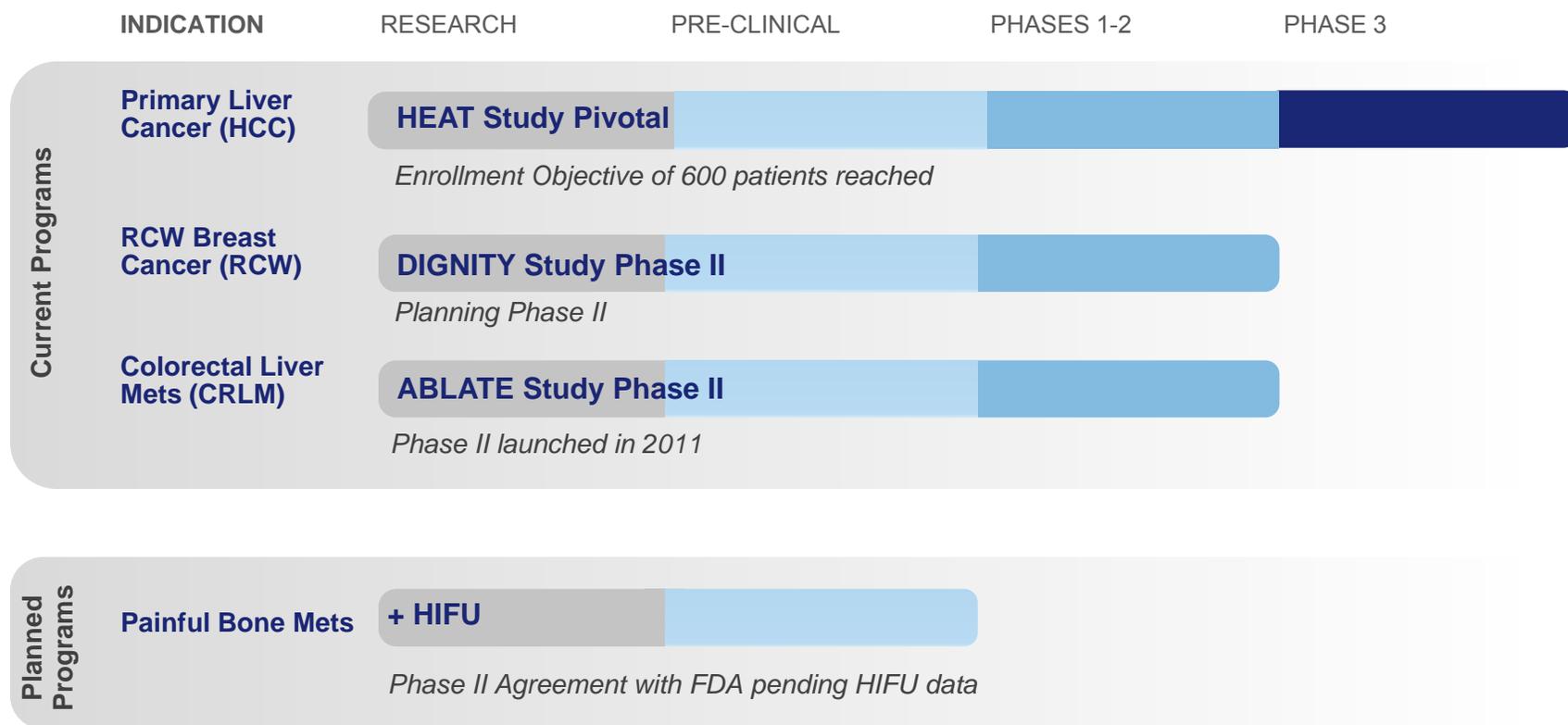


## ThermoDox Revenue Potential by Indication (in millions)



# ThermoDox Clinical Program

## Evaluating Multiple Oncology Indications



# ThermoDox + Hyperthermia

## 2nd Indication: RCW Breast Cancer



- 16 patients, 100% show clinical activity SD, PR, CR
- At 30 mg/m<sup>2</sup>, 6/6 subjects showed a clinical response with 2 Complete Responses

Limited Treatment Options



Complete Response



Phase I Data Presented at the ICHO Conference, Munich Ger, Ap'08

## DIGNITY Study

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

Completed with an Overall Response Rate of 45%

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

Commencing 2012

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

Eligibility:

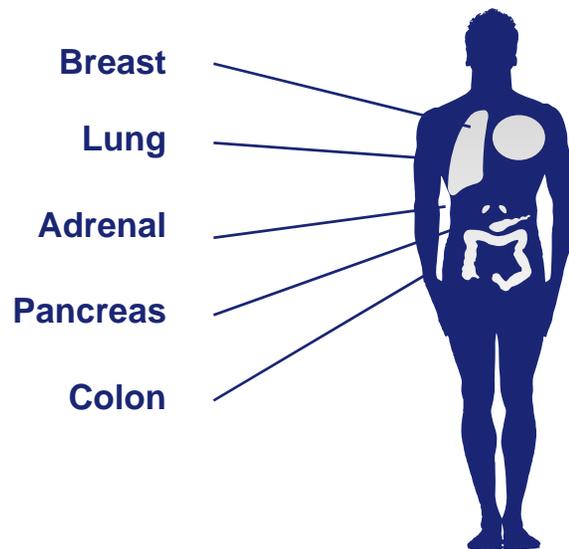
Breast Cancer patients who have recurrence of breast cancer on the chest wall who have had a mastectomy and prior treatment

Enrollment:

40 patients, 5 Institutions

# ThermoDox + RFA

3rd Indication: Liver Cancer Metastases (The ABLATE Study)



Initiated in two sites

1st patient enrolled in  
Q1- 2012

Expanding to 4 sites by  
mid year

## ThermoDox experience in 2 Phase I studies

- Liver cancer patients from 9 primary sites
- Local control and dose response relationship established

## Phase II Study of ThermoDox in Colorectal LCM patients

- Multiple center study, initiated Sept 2011
- 2 arm, randomized, RFA +/- ThermoDox
- Up to 88 patients to be enrolled

# ThermoDox Commercialization Strategy



## Global commercialization plans maximize shareholder value

- U.S. strategy is to market and sell directly
- Ex-U.S. strategy is through license agreements with Pharma Partner

## Japan license completed with Yakult Honsha in 2008

- \$4.5 million Signing Payments
- \$7.0 million in shared development costs
- High double digit royalty and milestones
- Supplier of ThermoDox at cost plus 35%

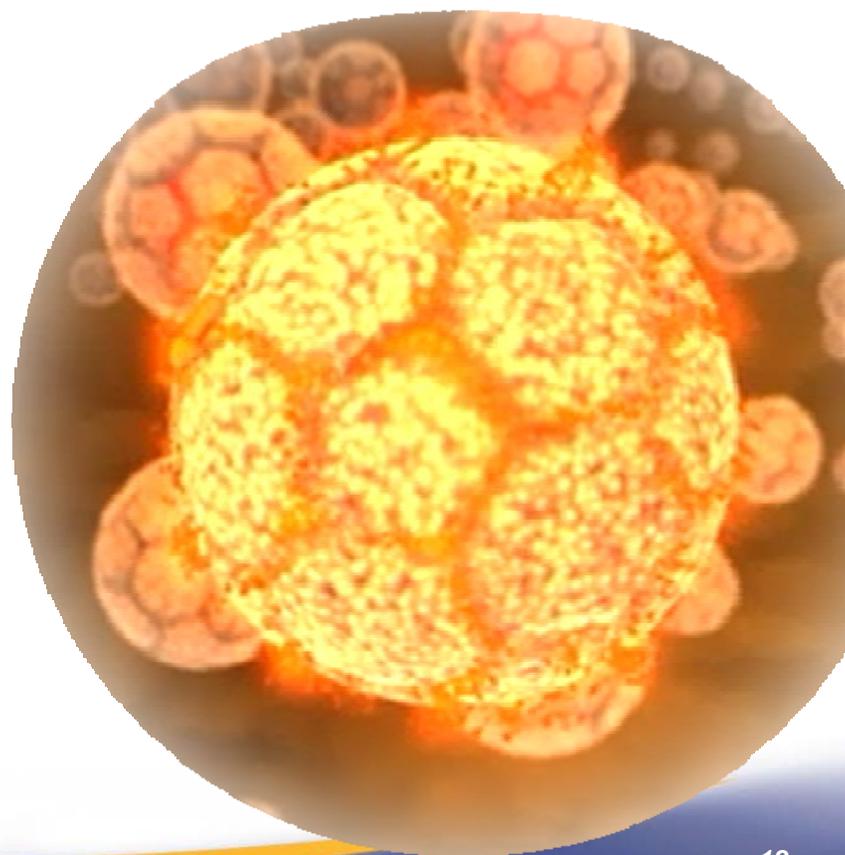
# Celsion Investment Profile

## Patent and Regulatory Protection

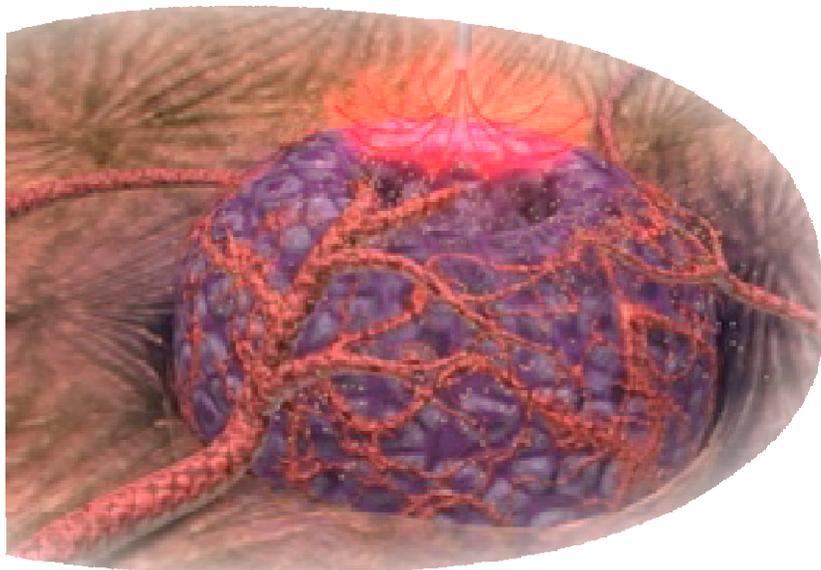
- Exclusive world-wide rights from Duke University Patent to 2018+
- Additional U.S Patent extends to 2021
- Orphan Drug Designation in U.S. and Europe provides 7 and 10 year exclusivity

## Technology platform expandable to a range of therapeutics and indications

- 4-lipid patent to 2024



# Celsion Investment Profile



## Balance Sheet Supports Major Operational Goals

- Top-line data from Phase III HCC Trial
- RCW Breast Cancer study
- Phase II CR Liver Mets study
- Completion of Commercial Manufacturing Development

## Experienced Management Team over 27 NDA's

- Drug Development Expertise
- Clinical Development and Operations
- CMC Development and Operations
- Regulatory and Quality
- Commercialization

# Financial Summary

As of September 30, 2011



<b>Cash &amp; Investments</b>	\$21.4 M
<b>Recent Financing Activity (Dec 2011)</b>	\$15.0 M
<b>Projected average cash usage per month</b>	~ \$1.7 M
<b>Common shares outstanding</b>	33.2 M
<b>52-week PPS Range</b>	\$1.69 - \$4.37
<b>Average Daily Trading Volume</b>	> 450 K
<b>Market Capitalization</b>	~ \$70 M



## Corporate Information

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