



NASDAQ: CLSN  
December, 2010

Innovation in oncology



# Safe Harbor Statement

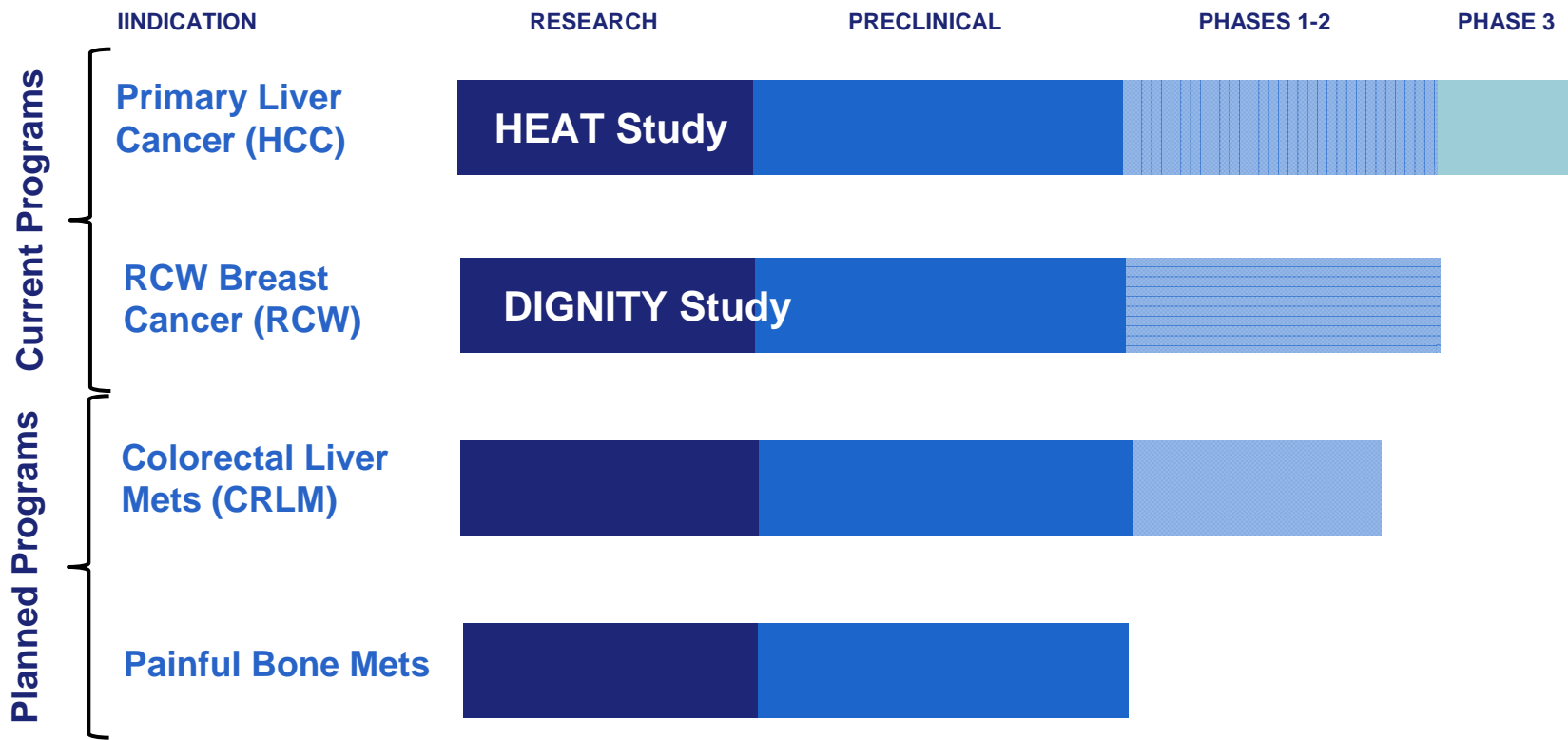
Except for historical information, the statements made in this presentation are forward-looking statements and are subject to certain risks, uncertainties and assumptions. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. These forward-looking statements represent our estimates and assumptions only as of the date of this presentation, and we do not intend to update any of these forward-looking statements to reflect circumstances or events that occur after the statement is made or to conform these statements to actual results. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the captions “Risk Factors” and “Forward-Looking Statements” in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q.

# Celsion Highlights

- Phase III oncology company addressing largest unmet need in oncology, HCC
- Technology provides highly effective targeted delivery of known chemotherapeutics
- ThermoDox<sup>®</sup> is in two registrational trials with accelerated commercialization potential
  - SPA granted
  - Fast Track Designation
  - 505(b)2 Eligible
  - Orphan Drug
  - NIH “Priority Trial” in Liver Cancer
- Represents billion dollar global market opportunity

# Commercially Focused Pipeline

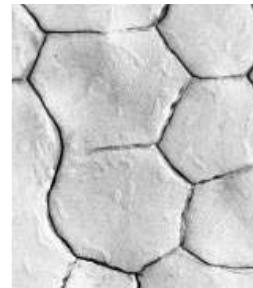
## ThermoDox Clinical Programs



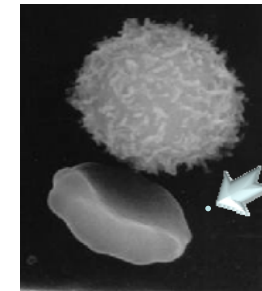
# Lysolipid Thermally-Sensitive Liposomes (LTSL) Optimizing Chemotherapeutics Through Improved Delivery

- Exclusive world-wide license from Duke University
- Intravenously administered, heat-activated liposomes or “artificial cells”
- At 100nm, liposomes concentrate through leaky blood vessels at the tumor site
- FDA approved heat energy sources release locally high concentration of chemotherapeutic
- High drug concentrations in target tissue overwhelm tumor resistance

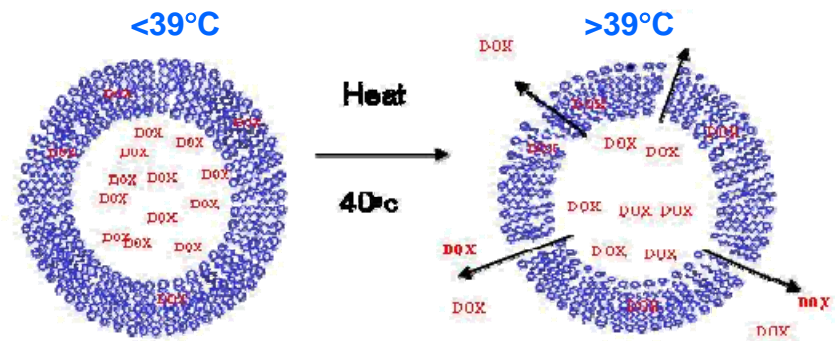
Artificial cells coined  
“nano-soccer ball”



ThermoDox is 100 nm,  
a Fraction of RBC &  
WBC

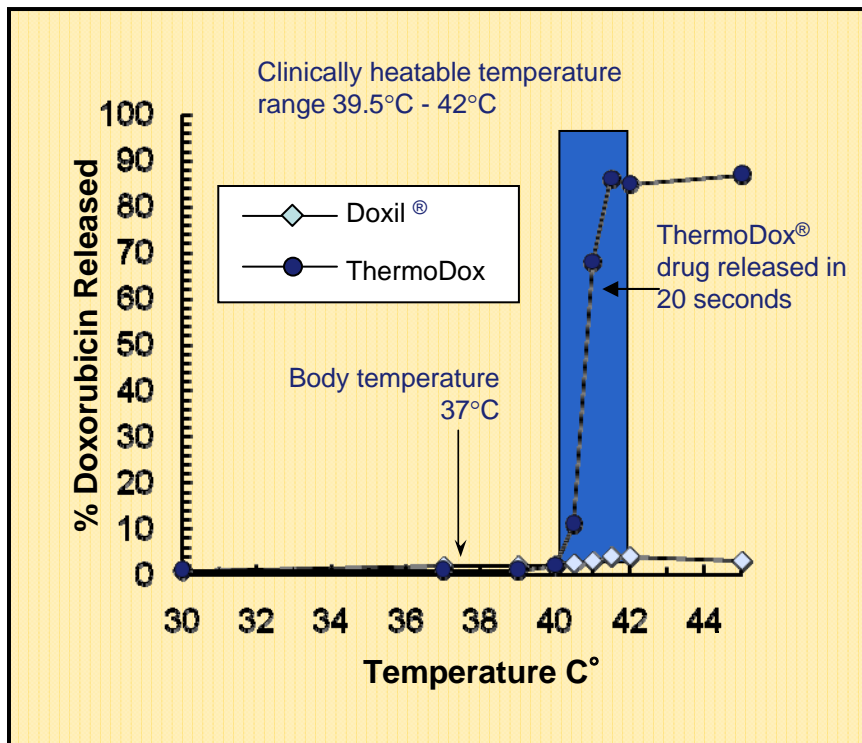


Rapid Release of Drug Through Pores

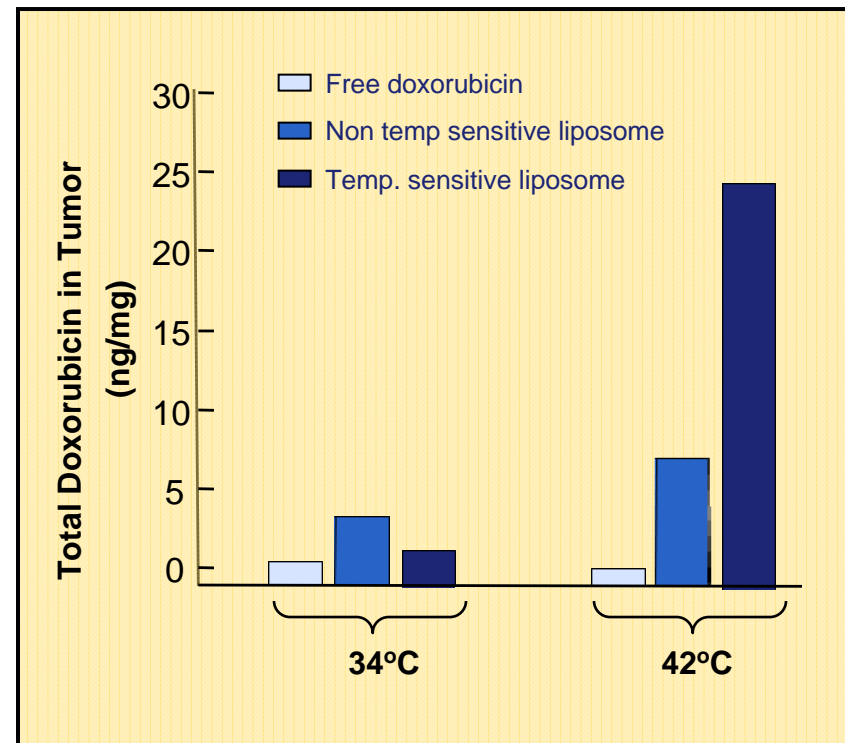


# ThermoDox Delivers High Concentrations of Chemotherapy Directly to Tumor

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

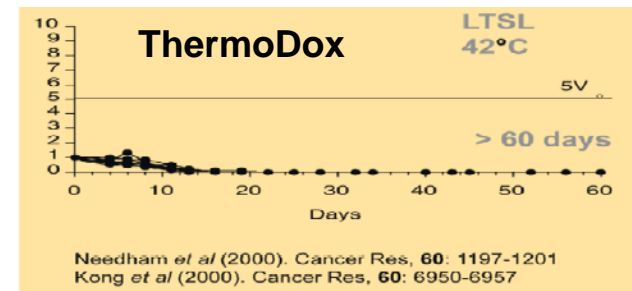
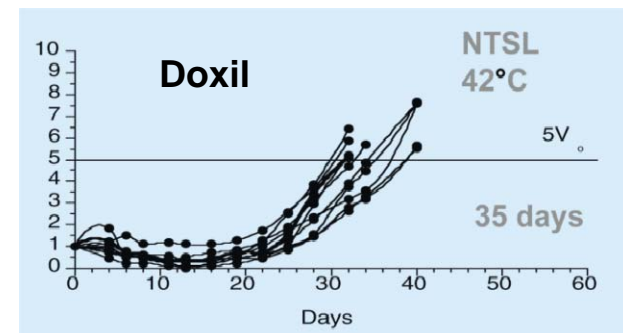
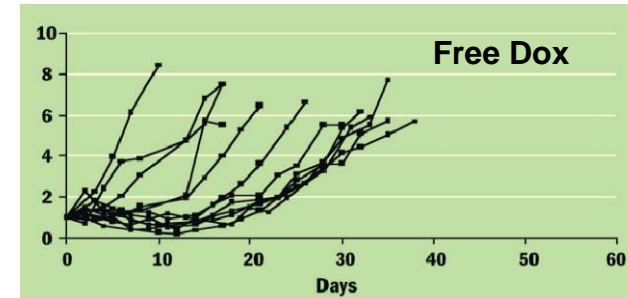
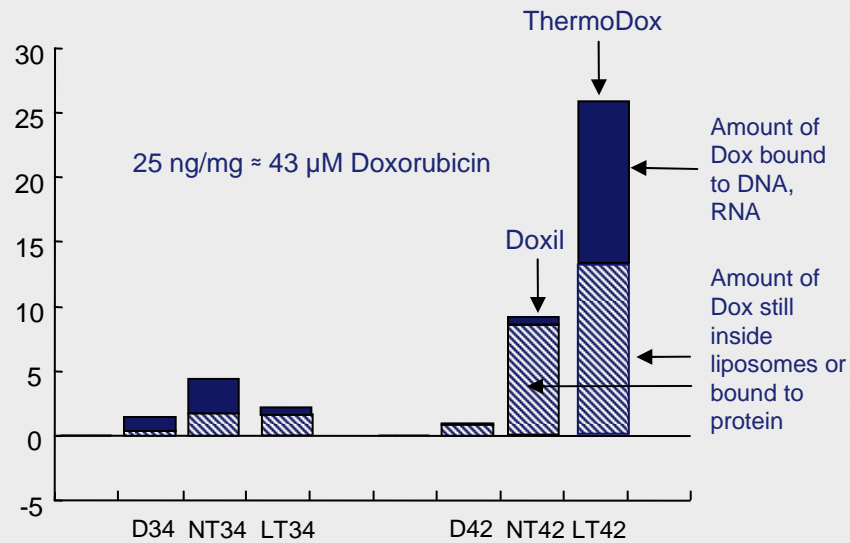


**IN VIVO** After 1 hour at 42°C, heat-sensitive formulation delivered most drug to tumor



# ThermoDox Provides Superior Therapeutic Activity

Mouse Tumors Heated at 42°C for 1 Hour After IV Administration



# Hepatocellular Carcinoma (HCC)

## High Unmet Global Need

- **#5 most prevalent cancer globally**
  - Age-adjusted HCC incidence rates tripled in US 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
- **High 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, cryoablation and radiation therapy**
  - RFA is the predominant treatment for non-resectable liver cancers with average local recurrence rate of 50%+/-
  - Efficacy is limited by tumor size ( $\leq 3$  cm)

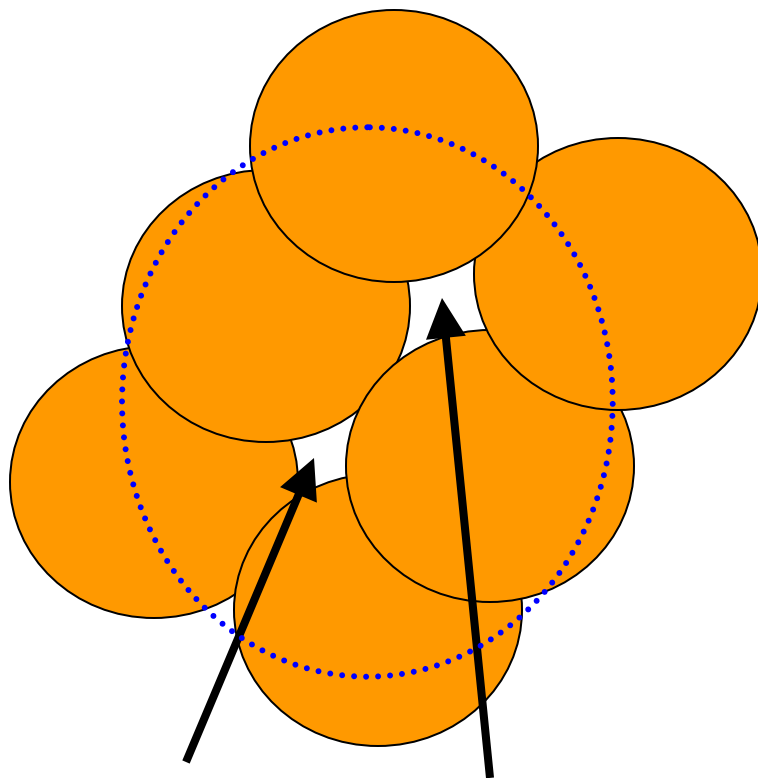




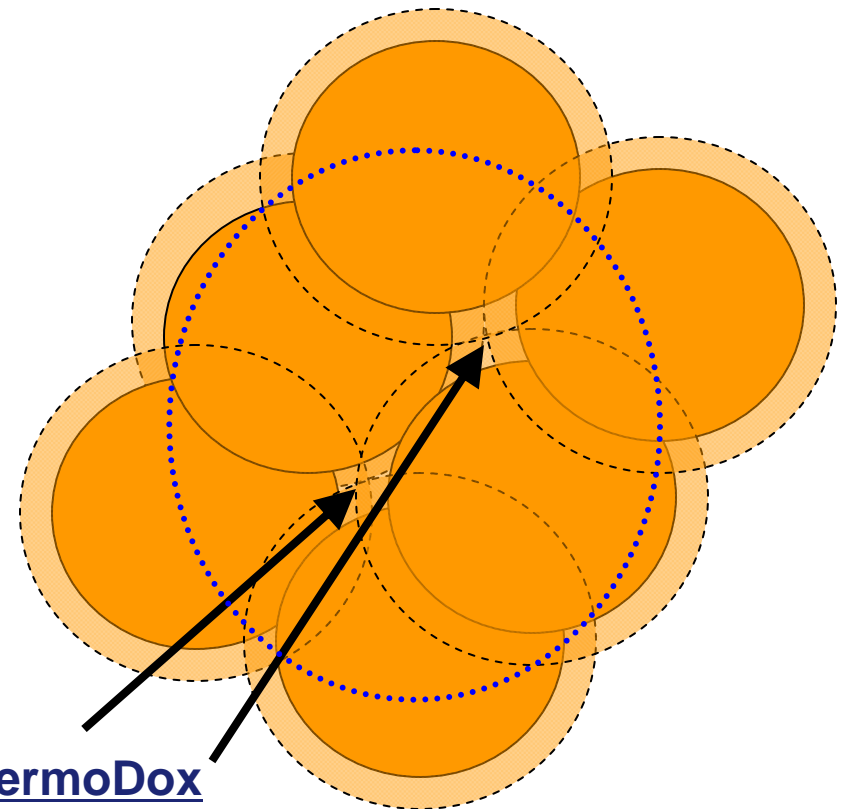
# ThermoDox / RF Ablation

## Greater Improvement for Larger Lesions

Larger lesions require multiple overlapping ablations:



Without ThermoDox  
Room for micro-metastases to survive

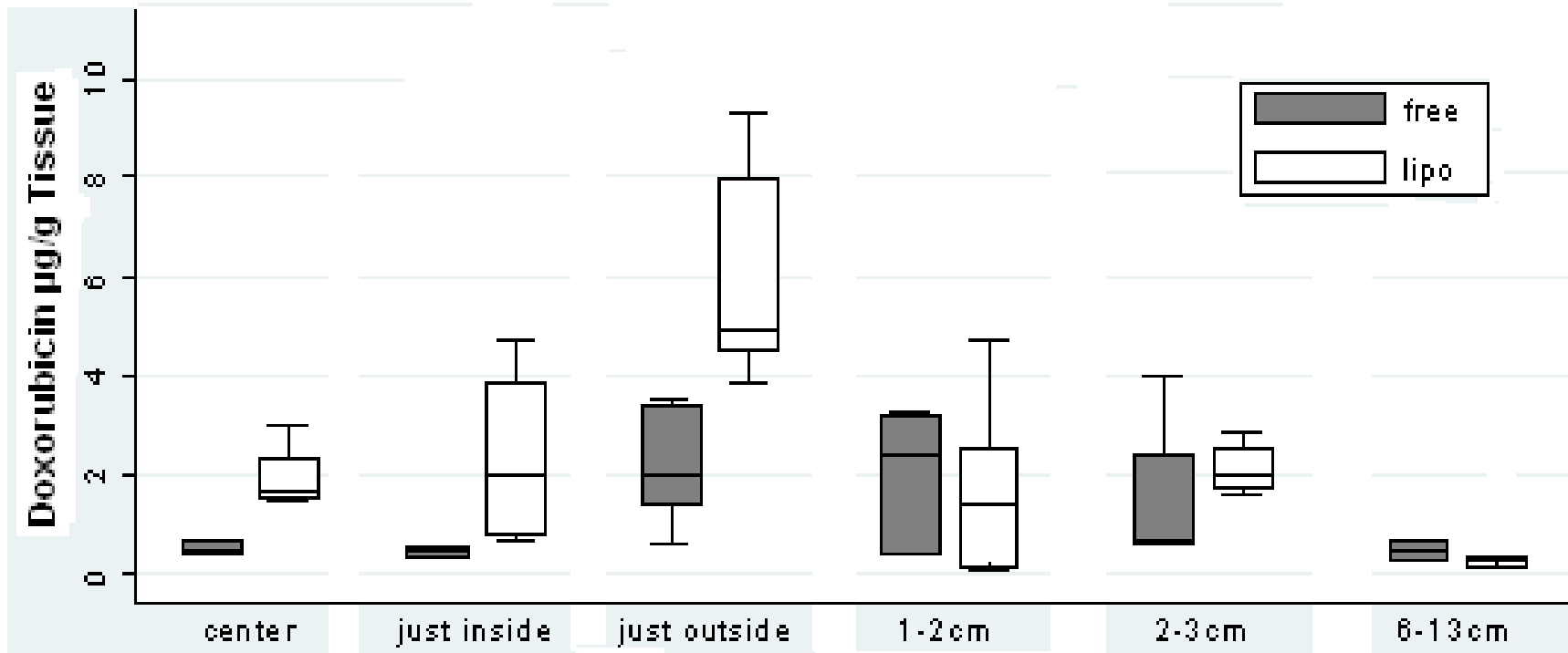


With ThermoDox  
Overlapping clefts address micro-metastases and expand kill zone

# RFA + ThermoDox

## Dox Deposition surrounding the ablation

Effect of RFA on Doxorubicin Deposition

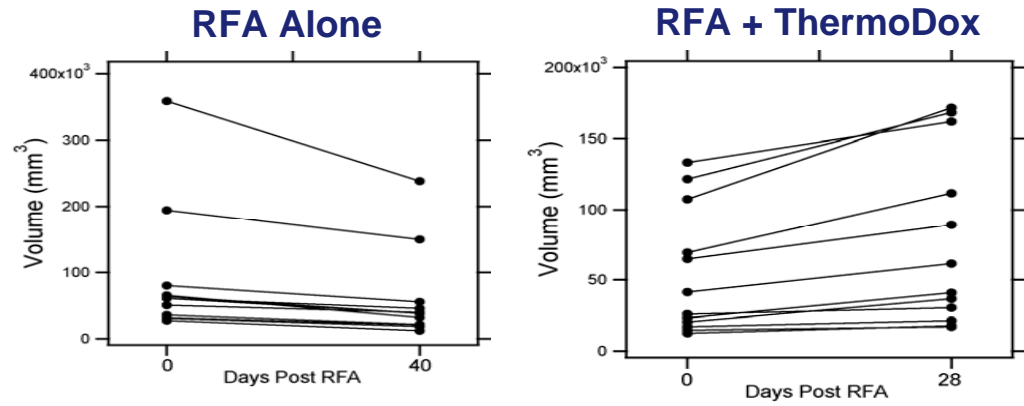


# Phase I Liver Cancer Results

## Highly Suggestive of Clinical Activity

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

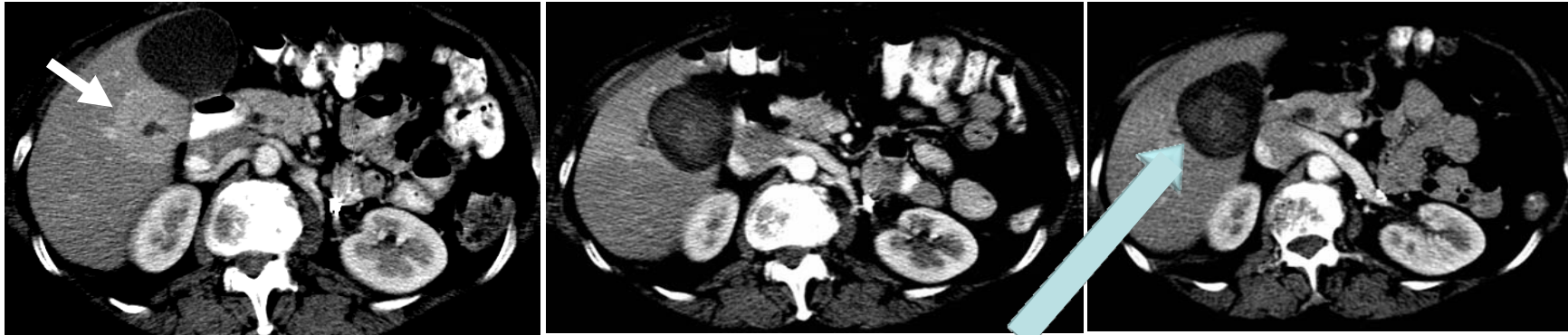
Ablation Volume increases with the addition of ThermoDox



Pre-treatment

11 weeks post-treatment

20 weeks post-treatment



Treatment Zone Increases

# Phase I Liver Cancer Results

## High Response Rate and Direct Dose Correlation

### Phase I

Dose (mg/m <sup>2</sup> )	Diagnosis	Time to progression (days)
20	MLC, n = 2 HCC, n = 1	32
30	MLC, n = 4 HCC, n = 2	53
40	MLC, n = 3 HCC, n = 3	145
50	MLC, n = 5 HCC, n = 1	185

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

# Phase I Liver Cancer Results

## Highly Suggestive of Clinical Activity in HCC Patients

Phase I Data HCC Only Patients

ThermoDox Dose (mg/mm)	Tumor Size (cm)	RFA Type P = percutaneous OS = open surgical	Time (days)	Treatment Failure	Median By Dose	Median Time ≤ 40 mg/mm	Median Time ≥ 50 mg/mm
20	3.1	P	80	Y	80	125	156
30	1.7	OS	188	Y	157		
30	2.9	OS	125	Y			
40	1.7	OS	85	Y	355		
40	2.1	OS	427	Y			
40	3.1	OS	355	Y			
50	6.5	P	374	Y	374	346	337
60	Not Reported	P	122	N	+229*		
60	2.5	OS	337	N			

\* At the 60 mg/mm dose level, no patients were found to be a treatment failure. Therefore, the 229 day median must be greater

# Phase I Liver Cancer Results

## Highly Suggestive of Clinical Activity

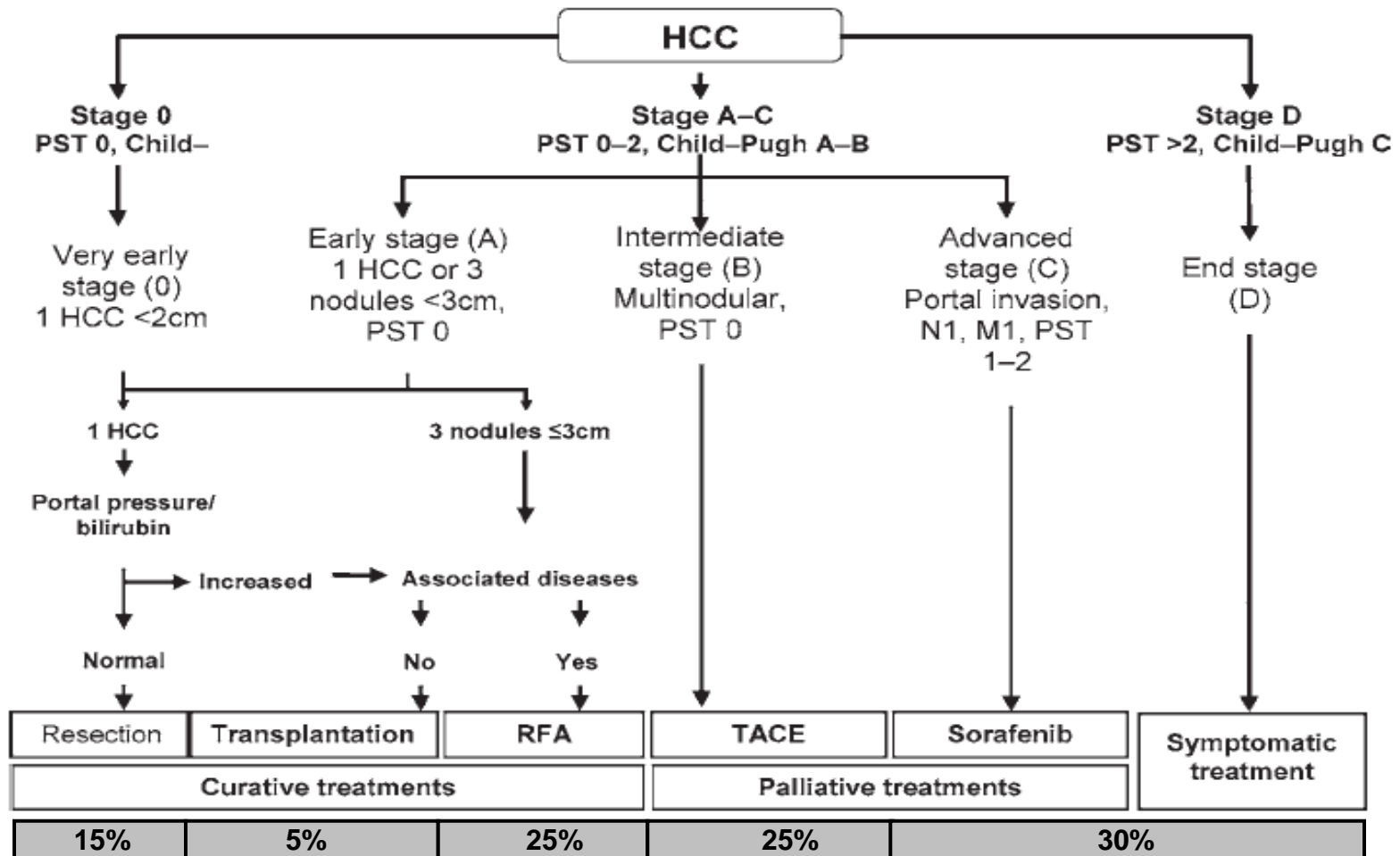
Manuscript: Poon, Borys, Expert Opinion, Pharmcother, 2009

**Table 3. Phase I RFA/LTLD time to treatment failure (TTF) by primary site, tumor size, RFA type, and LTLD dose.**

<b>Factor</b>	<b>Failed</b>	<b>Censored</b>	<b>Median TTF (days)</b>	<b>p-Value</b>
<b>Primary site</b>				
Liver	7	2	355	0.2227
Other	13	2	64	
<b>Tumor size</b>				
< 3.0 cm	6	2	156	0.4135
> 3.0 cm	14	1	86	
<b>RFA Type</b>				
Open surgical	6	1	188	0.4315
Percutaneous	14	3	80	
<b>LTLD dose</b>				
< 50 mg/mm	15	0	80	0.038
≥ 50 mg/mm	5	4	374	

# BCLC Staging System and Treatment

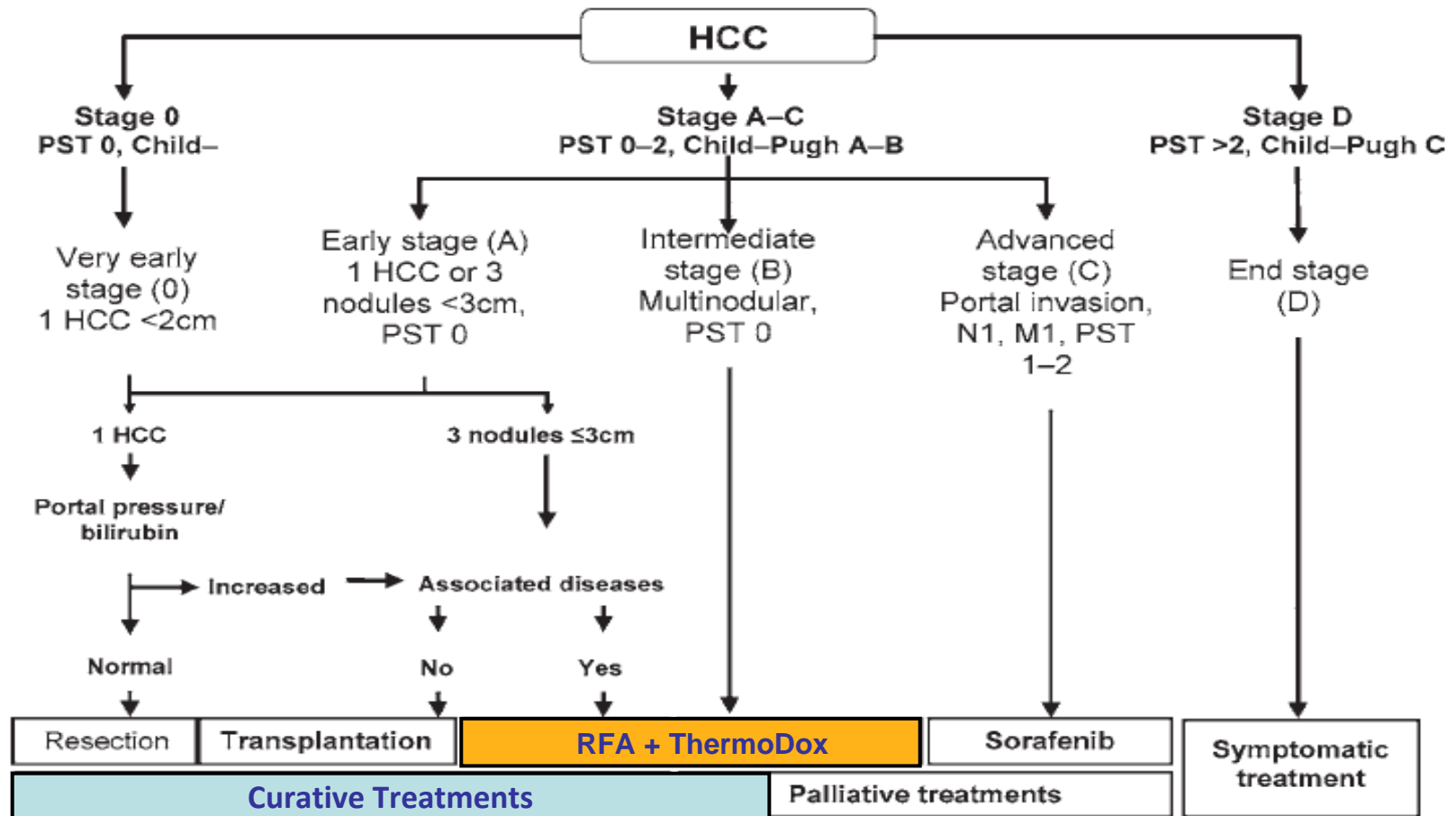
> 50% of Intent To Cure Receive RFA





# Modified BCLC Staging Criteria

ThermoDox Expands RFA Reach; Adds Order to Treatment Strategy



# Phase III HEAT Study

## Regulatory Strategy Accelerates Approval, Minimizes Uncertainty

**Accelerated Trial**

- SPA granted in 2008
- Accelerated endpoint

Ph 1 → Ph 3 supported by 10 International regulatory agencies  
PFS ~12 months after last patient

**Accelerated NDA**

- Fast track granted
- Priority review
- Orphan drug designation
- NIH-designated Priority Trial

Rolling NDA Submission in 2011/  
505b(2) Eligible  
6 months PDUFA  
7 year US Market Exclusivity  
10 year EU Market Exclusivity  
CDC growing healthcare issue

# Phase III HEAT Study

## Randomized, Double Blind, Placebo Controlled

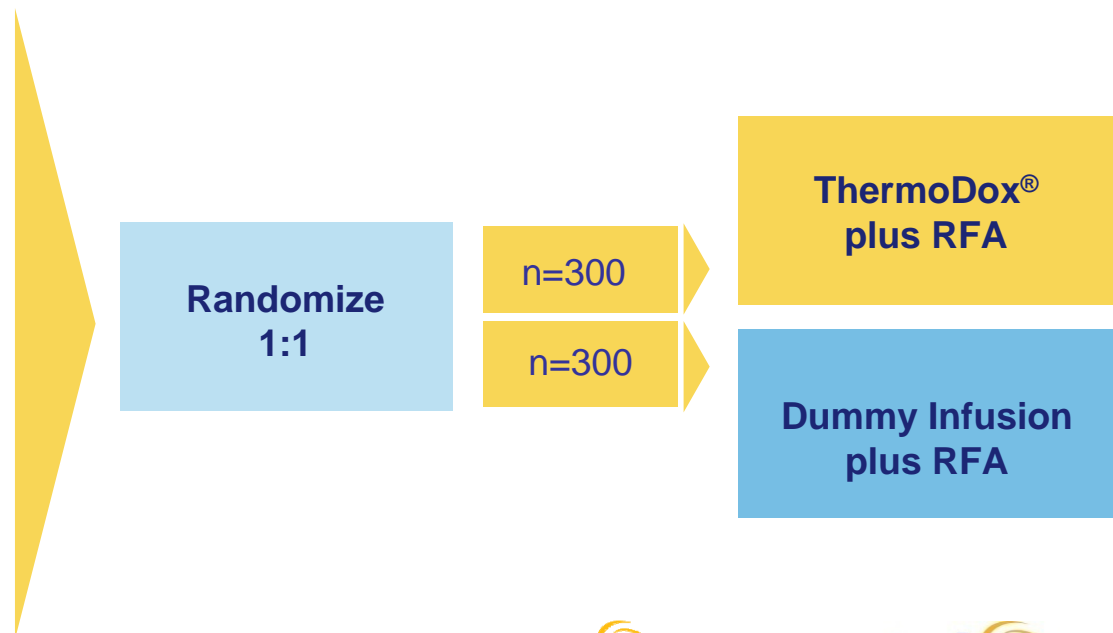
- **Primary Endpoint (per SPA):** Progression Free Survival
- **Secondary Endpoints:** Overall survival, time to local recurrence, time to definite worsening and safety

### Gen 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 vs >5-7
- RFA technique:
  - open surgical
  - laparoscopic or
  - percutaneous

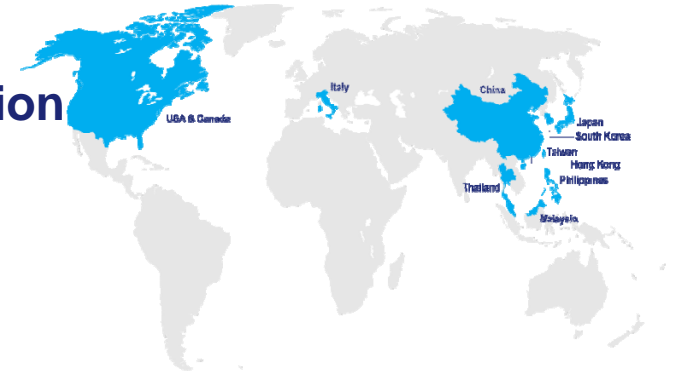


# Phase III HEAT Study

## Status & Milestones

### 76 sites enrolling in 11 countries

- **79% enrolled: 4–5 months to enrollment completion**
  - Rate may be favorably impacted by
    - Add'l clinical site in Italy added November 2010
      - National Referral Center for Liver Disease
    - Resumption of Japan enrollment
      - Enrollment in Japan paused for safety review by DMC
      - Regardless of timing, 60 patients required for PDMA review
      - Japan enrollment may continue after 600 pt. target reached
- **Blinded interim analysis at 190 PFS events expected Q2-2011**
  - 380 PFS events for primary end review
  - 372 Deaths for Overall Survival (OS) read out
- **Independent DMC evaluation conducted approx every 100 patients**
  - Latest recommendation to continue (September 2010)
  - Japan will continue with independent safety analysis



# ThermoDox

## 2nd Indication Recurrent Chest Wall (RCW) Breast Cancer

- **Breast cancer recurring in the chest wall affects ~35,000 post mastectomy patients in the US and Europe**
  - Up to 40% of women undergoing a mastectomy as primary treatment will experience local recurrence
  - Reappearance of cancer in the ipsilateral breast, chest wall, or skin overlying the chest wall
  - 60% of patients present with ulceration, bleeding and pain, highly debilitating and visible cancer
- **Prognosis is poor because most patients will go on to develop metastatic disease**
  - Limited treatment options – no standard of care
  - Radiation alone and systemic chemotherapy are ineffective
  - Local tumor control is a primary objective in these patients



# ThermoDox + Hyperthermia for RCW

## Local Treatment Local Control



- ThermoDox 50mg/m<sup>2</sup> IV in ½ liter D5W
- Hyperthermia applied to local lesion
- 45° C for 60 minutes
- Heat penetration 2-4 cm

- Doxorubicin is concentrated at the lesion
- Multiple cycles, up to 6

# Duke Phase I Data: ThermoDox for RCW



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

Limited Treatment Options

Complete Response



After 3 Cycles



After 4 Cycles

# RCW Phase I/II Trial Design

## The DIGNITY Study

- **Phase I:** MTD of ThermoDox + mild hyperthermia.
- **Phase II (Registrational Trial):** To determine the Durable Complete Local Response rate following treatment with ThermoDox + mild hyperthermia.
  - Phase I enrolled, 50mg/m<sup>2</sup> dose established pending DMC agreement

### Eligibility:

- Breast Cancer patients who have documented recurrence of breast cancer on the chest wall (or its overlying skin), who have had a mastectomy radiation and 2 courses of chemotherapy

### Stratification:

- None

Phase I & II

N = 9

N = 100

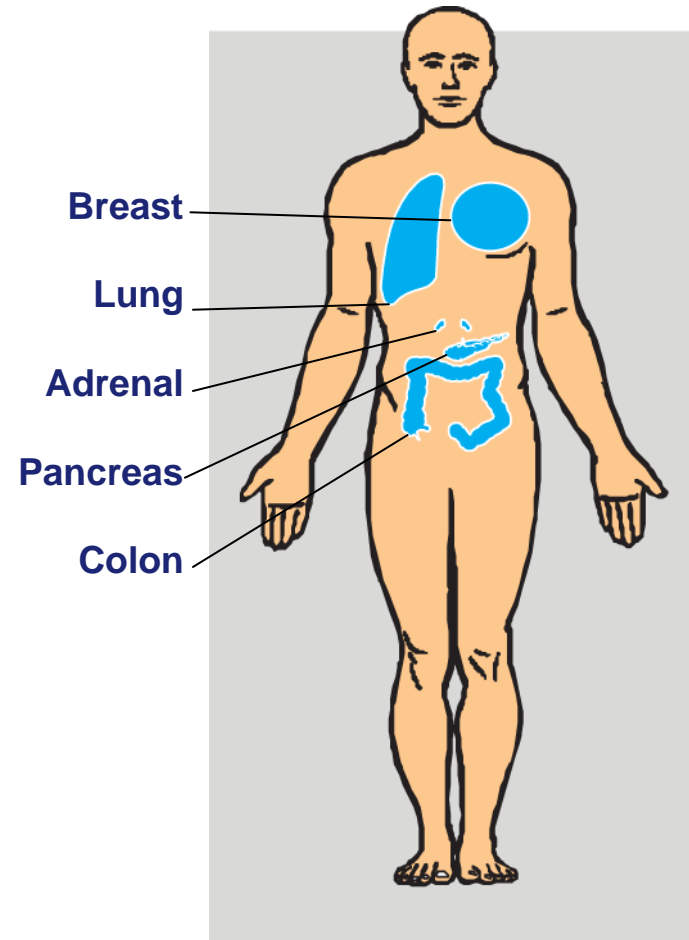
ThermoDox<sup>®</sup> plus hyperthermia



# ThermoDox

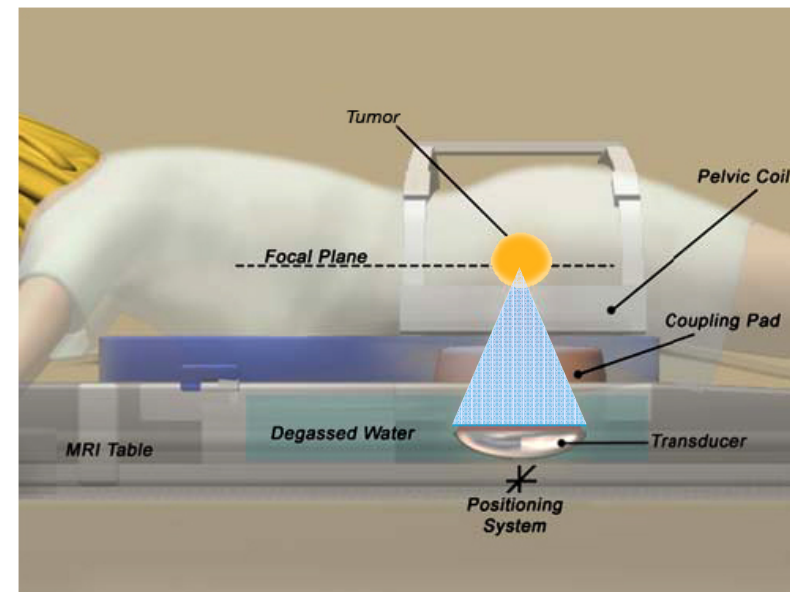
## 3rd Indication Metastasis Liver Cancer (MLC)

- **ThermoDox experience in 2 Phase I studies**
  - Treated 24 metastatic liver cancer patients from 9 primary sites
  - Local control and dose response relationship established
- **Phase II Study of ThermoDox in Colorectal MLC patients**
  - Multiple center study to commence following HEAT Study enrollment
  - Up to 92 patients to be enrolled
  - Initiation in Q1-2011



# Phillips Joint Research Agreement: ThermoDox + MRI guided HIFU

- **ThermoDox in combination with High Intensity Focused Ultrasound (HIFU) for non-invasive treatment of inaccessible, difficult to treat solid tumors**
- **Broadens ThermoDox's reach to indications with significant need**
  - Bone metastases 4<sup>th</sup> indication, 240K US incidence
  - Pancreatic cancer 5<sup>th</sup> indication, 30K US incidence
- **Phase II protocol agreement**
  - FDA Meeting scheduled Feb 2011



# Studied Cancers Represent High Unmet Need

## ThermoDox addresses \$billion + market

Region	Indication	2012	2013	2014	2015	2016
USA	HCC	28	29	31	32	34
USA	MLC	0	360	370	381	393
Europe	HCC	37	38	39	40	42
Europe	MLC	0	370	382	393	405
Asia-Pac	HCC	0	0	450	472	495
<b>Total Incidence</b> (thousands)		<b>66</b>	<b>797</b>	<b>1,272</b>	<b>1,318</b>	<b>1,369</b>
<b>Revenue Potential</b> (millions)		<b>\$20</b>	<b>\$236</b>	<b>\$680</b>	<b>\$1,160</b>	<b>\$1,750</b>
Region	Indication	2012	2013	2014	2015	2016
USA	RCW (NDA 2012)	13	13	14	14	15
Europe	RCW	23	24	25	26	26
<b>Total Incidence</b> (thousands)		<b>36</b>	<b>37</b>	<b>39</b>	<b>40</b>	<b>41</b>
<b>Revenue Potential</b> (millions)		<b>\$85</b>	<b>\$264</b>	<b>\$450</b>	<b>\$740</b>	<b>\$750</b>

Addressable Incidence by Approval Year

# ThermoDox Commercialization Strategy

- **Global commercialization plans maximize shareholder value**
  - US strategy is to market and sell directly
  - Ex-US strategy is through license agreements with Pharma. partners
- **Japan license completed with Yakult Honsha in December 2008**
  - \$2.5 million at signing and
  - \$6.0 million in shared development costs
  - \$18 million upon approval
  - Terms focused on commercial sales:
    - High double digit royalty
    - Supplier of ThermoDox at cost plus 35%



# Financial Summary

As of 9/30/2010

- **Cash and equivalents** **\$ 3.2 M**
- **Committed equity financing (June 2010)** **\$ 15.0 M**
  - Transactions at will over 24 months at discount of 5% - 6%
  - Two draws in 2010 aggregating \$1.4 M
- **Expected 12 month operating average cash usage per month** **~ \$1.3 M**
- **Common shares outstanding** **12.7 M**
- **52 Week PPS Range** **\$ 2.65 - \$ 5.63**

# Management Team

<b>Michael H. Tardugno</b> President and Chief Executive Officer	Mylan Technologies Inc, Songbird Hearing, Bristol-Myers Squibb, Bausch & Lomb, Abbott Laboratories
<b>Nicholas Borys, MD</b> Vice President and Chief Medical Officer	Molecular Insight Pharmaceuticals, Cytogen Corp, Anthra Pharmaceuticals, Amersham Healthcare, Hoffmann La-Roche
<b>Jeffrey W. Church</b> Vice President and CFO	Alba Therapeutics, Novavax, GenVec, Meridian Medical Technologies
<b>Robert Reed, PhD</b> Exec Director, CMC & Technical Ops	XenoPort, Merck &Co, Liposome Company
<b>Raj Prabhakar</b> Exec Director, Business Development	Osiris Therapeutics, Protiveris, Swander Pace Capital, Wasserstein Perella, Harvard Medical School

# Near Term Milestones

## **Lead ThermoDox Program - HCC**

Ph III HCC Trial Enrollment Completion

Ph III HCC Blinded Interim Analysis (190 PFS events)

Rolling NDA Submission for HCC

Ph III HCC Final Analysis (380 PFS events)

2nd License Agreement for ThermoDox

## **ThermoDox Pipeline Programs**

Complete Ph I RCW Dignity Trial

IND filing Ph I/Ph II Protocol for Bone Met Study

Initiate Ph II MLC Study

# Celsion Highlights

- Phase III oncology company addressing largest unmet need in oncology, HCC
- Technology provides highly effective targeted delivery of known chemotherapeutics
  - Significantly increases likelihood of technical success
  - Reduces regulatory risk
  - Accelerates market adoption
- ThermoDox is in two Registrational trials with rolling NDA expected to begin in 2011
- Target indications represent billion dollar global market opportunity
- Technology platform expandable to include additional therapeutics and indications
- Management team focused on execution



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