

# Cowen and Company 32<sup>nd</sup> Annual Health Care Conference

March 5 - 7, 2012

**NASDAQ: CLSN** 

#### **Presented by:**

Michael H. Tardugno

President and Chief Executive Officer

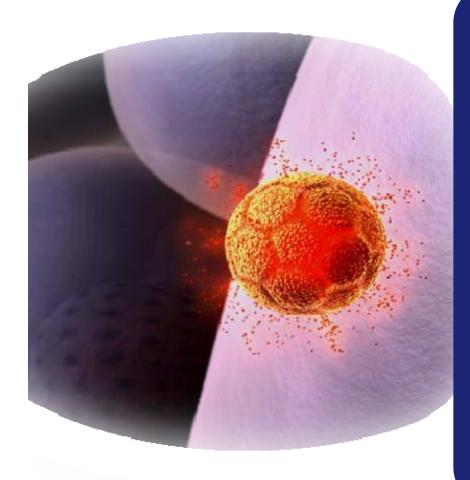
### **Safe Harbor Statement**



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.





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® 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



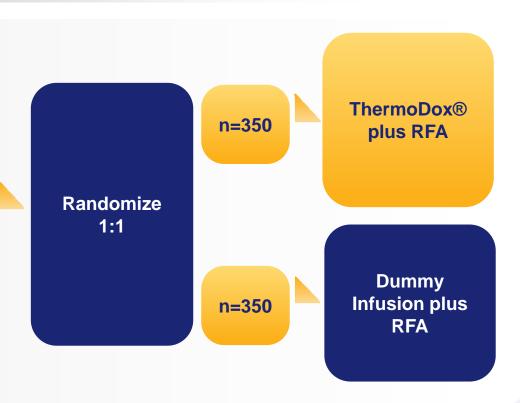
Primary Endpoint:	Progression Free Survival		
Secondary Endpoints:	Overall Survival, Time to Local Recurrence, Time to Definite Worsening, and Safety		

#### **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



## Fastest Path Regulatory Strategy



Unmet	#1 unaddressed Cancer NIH "Priority Trial"	HBV & HCV put millions at risk, globally  CDC "growing global healthcare issue"
Accelerated Trial	Agreed to SPA Accelerated endpoint	Supported by 10 regulatory agencies  Progression Free Survival (PFS)
Accelerated NDA	Fast track granted Priority review	Rolling NDA begins in 2012 6 months PDUFA
	505(b)(2) eligible for U.S. EU, China, Taiwan, S. Korea	Pre-clinical studies sufficient to support NDA  Phase III trial as a stand alone for filing

Interim Analysis by the DMC Supports Continuation





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

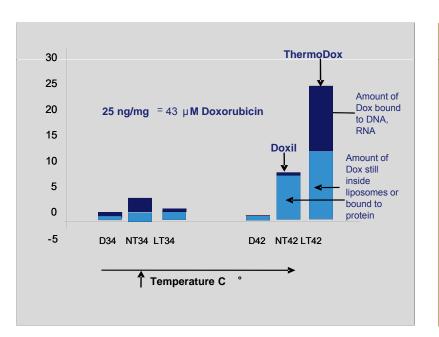
Top Line Data projected for year end 2012

### **ThermoDox Pre-Clinical Studies**

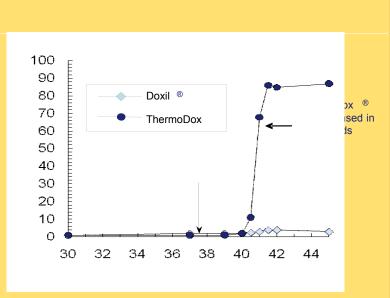


Chemotherapy Directly to Tumor with Superior Activity

**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

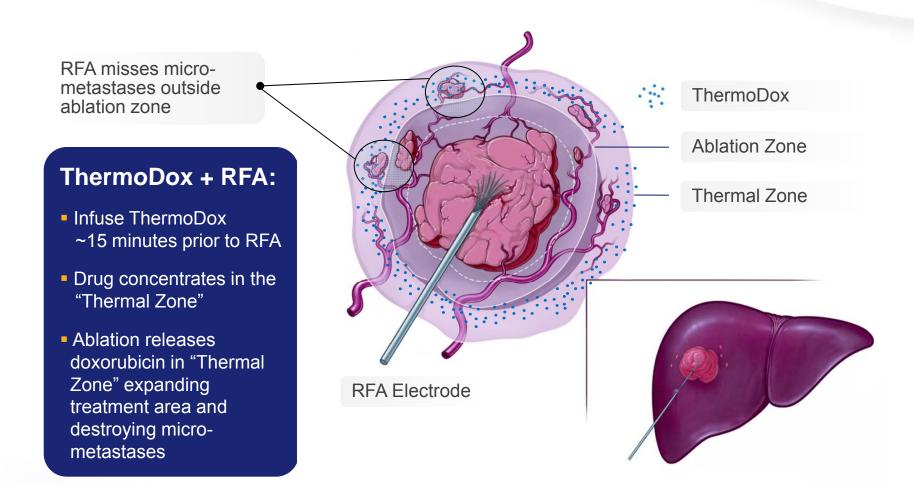
#### Local therapies include:

- RFA, TACE, ethanol injection, and radiation therapy
- RFA is the dominant treatment for nonresectable 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



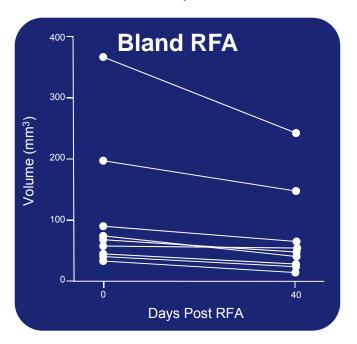
Expanding the Treatment Zone Addresses RFA Limitations

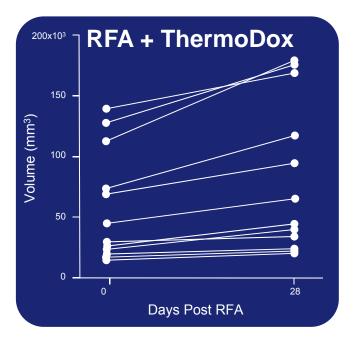


#### **Phase I Liver Cancer Results**

Highly Suggestive of Clinical Activity

- 2 Clinical Sites: NCI (US) and Queen Mary Hospital (HK)
- Single dose treatment; 50mg/m² MTD established
- No unanticipated SAE or AE experienced







Pre-treatment



11 weeks post-treatment



20 weeks post-treatment



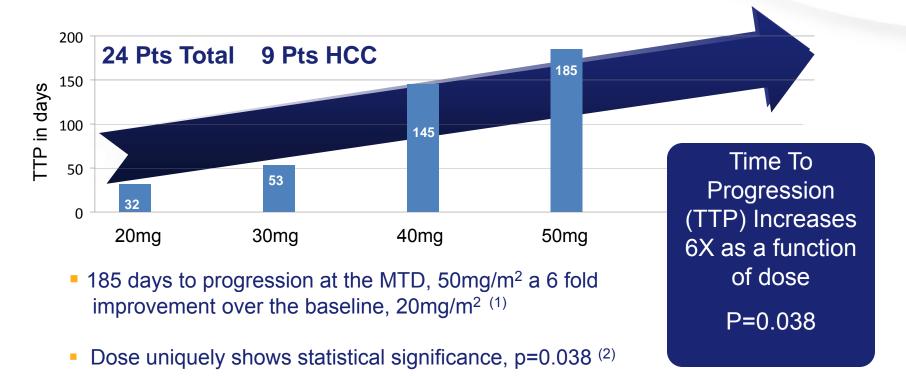
Treatment Zone Increases

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



 In the HCC subgroup, TTP more than doubles at therapeutic doses, 50 and 60mg/m<sup>2</sup>

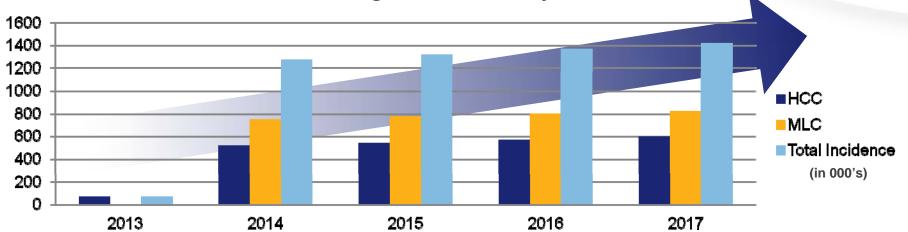
<sup>(1)</sup> Phase I data presented at IHPBA Conference, Mumbai, India, February, 2008, Dr. R Poon

<sup>(2)</sup> Manuscript: Poon, Borys, Expert Opinion, Pharmcother, 2009

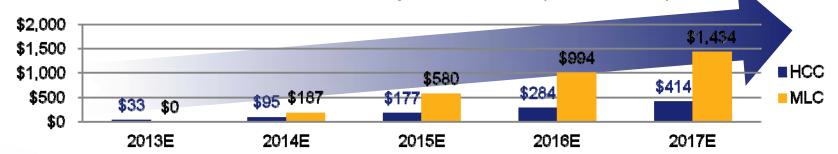
## **Studied Liver Cancers Revenue Potential**



Addressable Incidence Growing +5% Annually WW







## **ThermoDox Clinical Program**



## **Evaluating Multiple Oncology Indications**

	INDICATION	RESEARCH	PRE-CLINICAL	PHASES 1-2	PHASE 3
Current Programs	Primary Liver Cancer (HCC)	HEAT Study Pivot Enrollment Objective	e of 600 patients reached		
	RCW Breast Cancer (RCW)	DIGNITY Study Pl Planning Phase II	hase II		
	Colorectal Liver Mets (CRLM)	ABLATE Study Ph			
Planned Programs	Painful Bone Mets	+ HIFU  Phase II Agreement v	with FDA pending HIFU da	ta	

## 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



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



Completed with an Overall Response Rate of 45%

Ph I

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

Commencing 2012



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

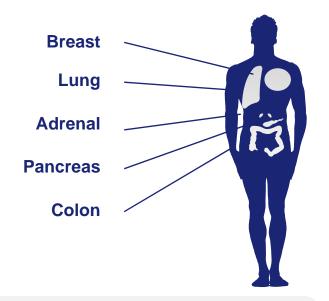
#### **Enrollment:**

40 patients, 5 Institutions

### ThermoDox + RFA



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



# ThermoDox experience in 2 Phase I studies

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

Initiated in two sites

1st patient enrolled in Q1- 2012

Expanding to 4 sites by mid year

# 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%

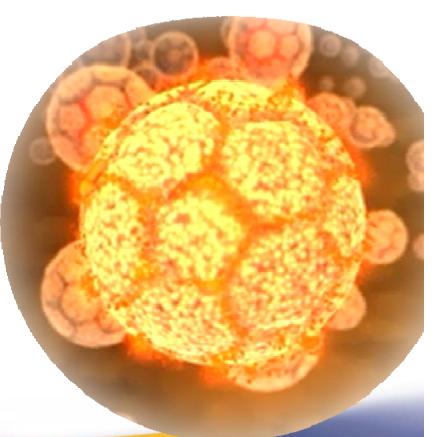


#### Patent and Regulatory Protection

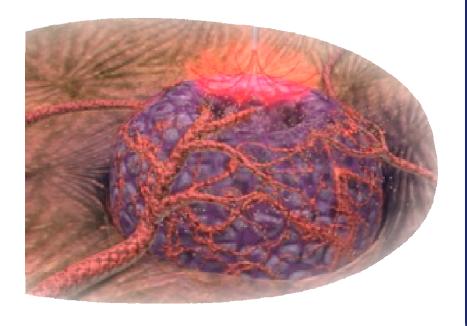
- Exclusive world-wide rights from Duke
   University Patent to 2018+
- Additional U.S Patent extends to 2021
- Orphan Drug Designation in U.S. and Europe provides 7 and 10 year exclusivity

Technology platform expandable to a range of therapeutics and indications

4-lipid patent to 2024







# **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



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



## **Corporate Information**

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**NASDAQ: CLSN**