Delcath Systems, Inc.

Advancing Targeted Drug Delivery

Investor Presentation

August 2009

www.delcath.com
www.livercancertrials.com

Nasdaq: DCTH

Forward-looking Statements

This presentation contains forward-looking statements, within the meaning of federal securities laws, related to future events and future financial performance. Many of these statements involve known and unknown risks and uncertainties, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. These risks are described in Delcath's 2008 Annual Report on Form 10-K and in its Quarterly Reports on Form 10-Q. All of Delcath's plans and objectives made in this presentation are based upon management's current expectations, but many such expectations are based upon economic, clinical and regulatory uncertainties, and thus, may differ materially from actual results.

Our Mission

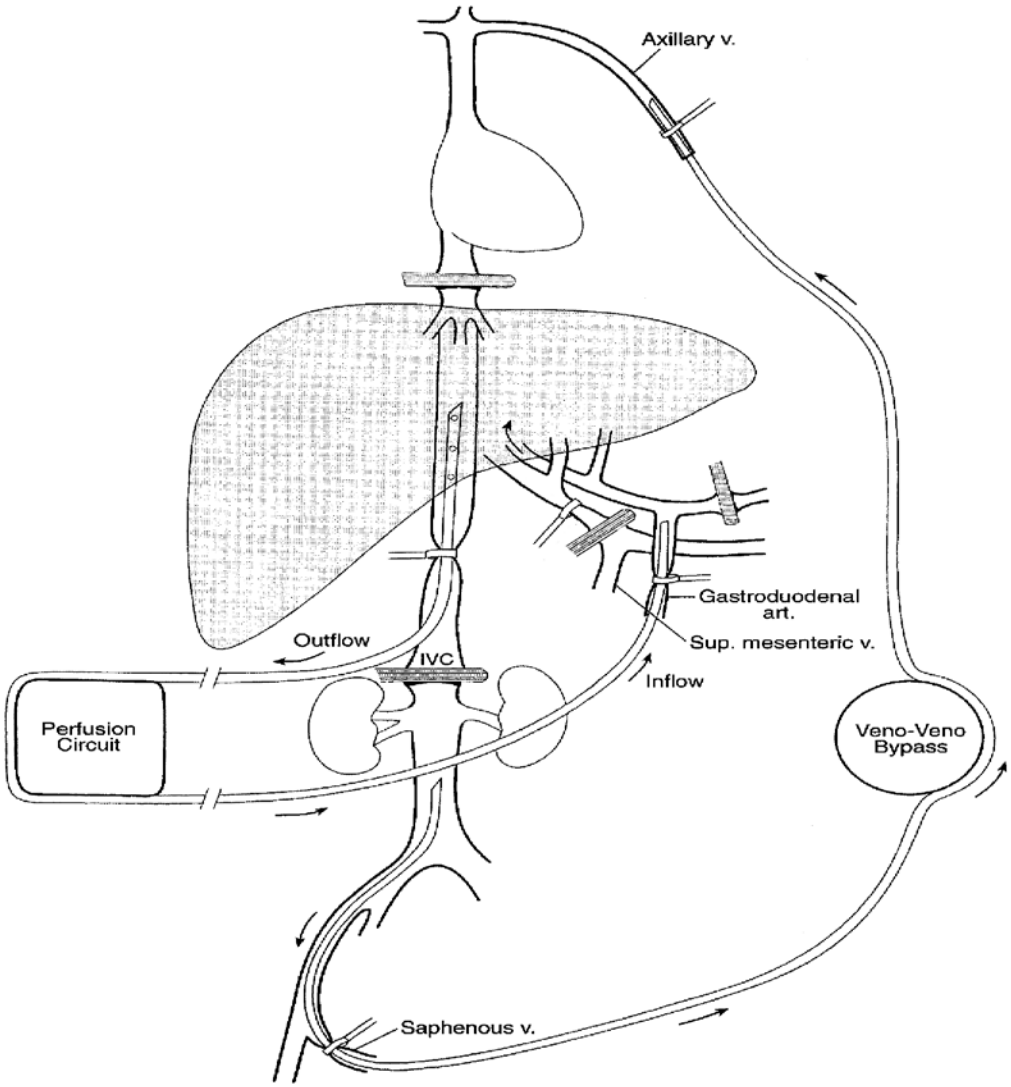
Emerge as the Leader in Ultra High Dose Regional Targeted Chemotherapy

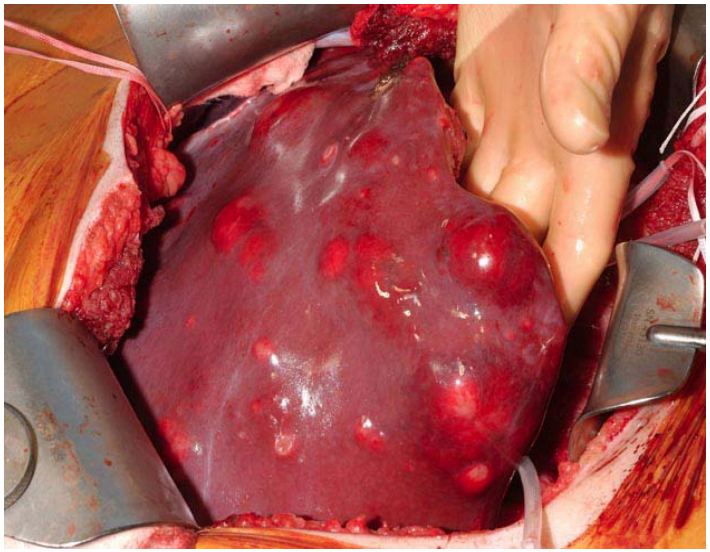
- Establish Delcath's *Percutaneous Hepatic Perfusion (PHP™)* technology as the new paradigm first line treatment for unresectable liver cancers
- Become a global standard neo-adjuvant and adjunctive treatment option for all liver diseases including HCV and HBV
- Generate increasing levels of shareholder value and returns

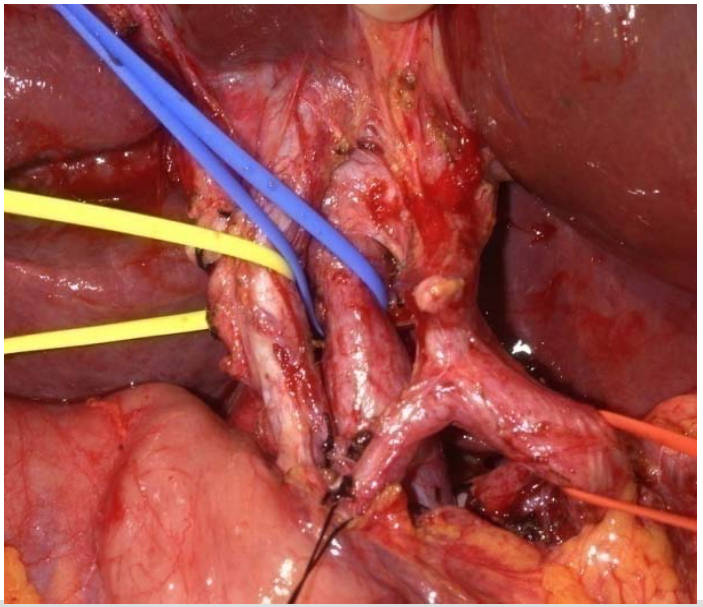
Liver Cancer
High Unmet Medical Need

- Cancers of the liver are the 5th most common type of cancer and the 3rd leading cause of cancer-related deaths
- Approximately 250,000 cases of primary or secondary cancer of the liver are diagnosed each year in the U.S.
- Approximately 2,600,000 cases globally
- Less than 10% of liver cancer patients qualify for surgery, currently the most effective treatment option
- Approximately 50% of all end stage cancer patients will show some incidence of liver metastases

PHP evolved from Open Surgical IHP







Proof of Concept - IHP

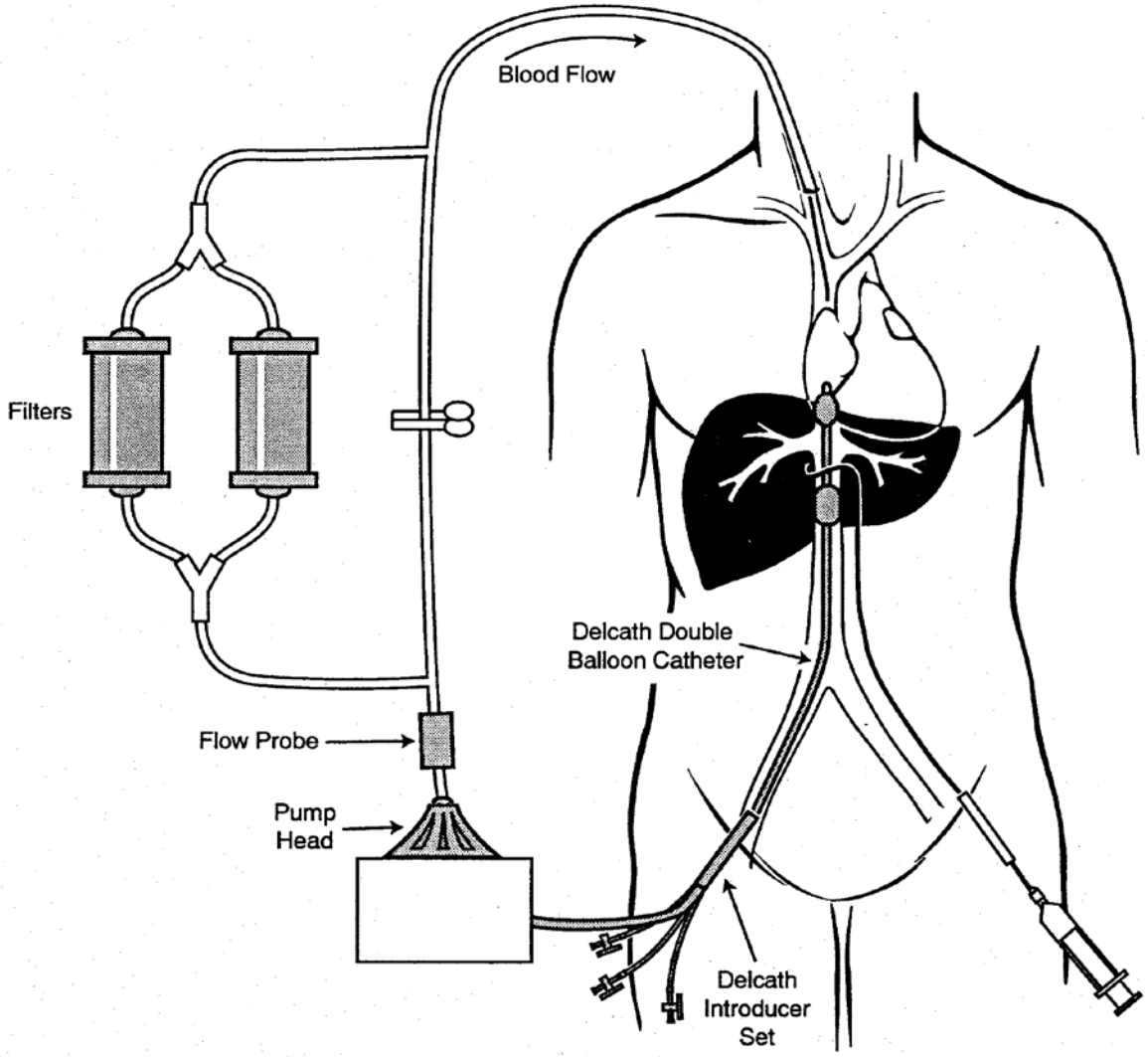
A Solution to an Unmet Need

- Delivering cancer drugs directly to the tumor site can allow for dramatic *dose escalation* of drug agents
- Regional therapy capitalizes on the *unique vascular anatomy* of the liver
- *Eliminates or dramatically reduces systemic toxicities* by isolating the circulation of the organ or region from the patient's circulatory system
- Higher dosing results in *improved efficacy*

Shortcomings of Open Surgical Perfusion

- Highly invasive surgical procedure – very high morbidity
- Surgery can be performed only once
- Hepatic toxicities limited drug dosing
- Liver disease ultimately recurred after surgical IHP

Innovation: The Delcath PHP System™



Melphalan Dosing Levels

Multiple Myeloma (label)	**0.25 mg/kg[1]**
Chemoembolization	**0.62 mg/kg[2]**
Surgical Isolated Hepatic Perfusion	**1.5 mg/kg[3]**
Percutaneous Hepatic Perfusion (PHP™)	**3.0 mg/kg**
Myeloablation	**2.5-3.5 mg/kg**

- Drug dosing over 10x higher than FDA approved dose via traditional i.v. systemic chemotherapy
- Dose delivered to tumor is estimated at 100x that of systemic i.v. chemotherapy
- Filters remove drug from blood, reducing systemic toxicities to levels at or below that of low dose i.v. systemic infusion

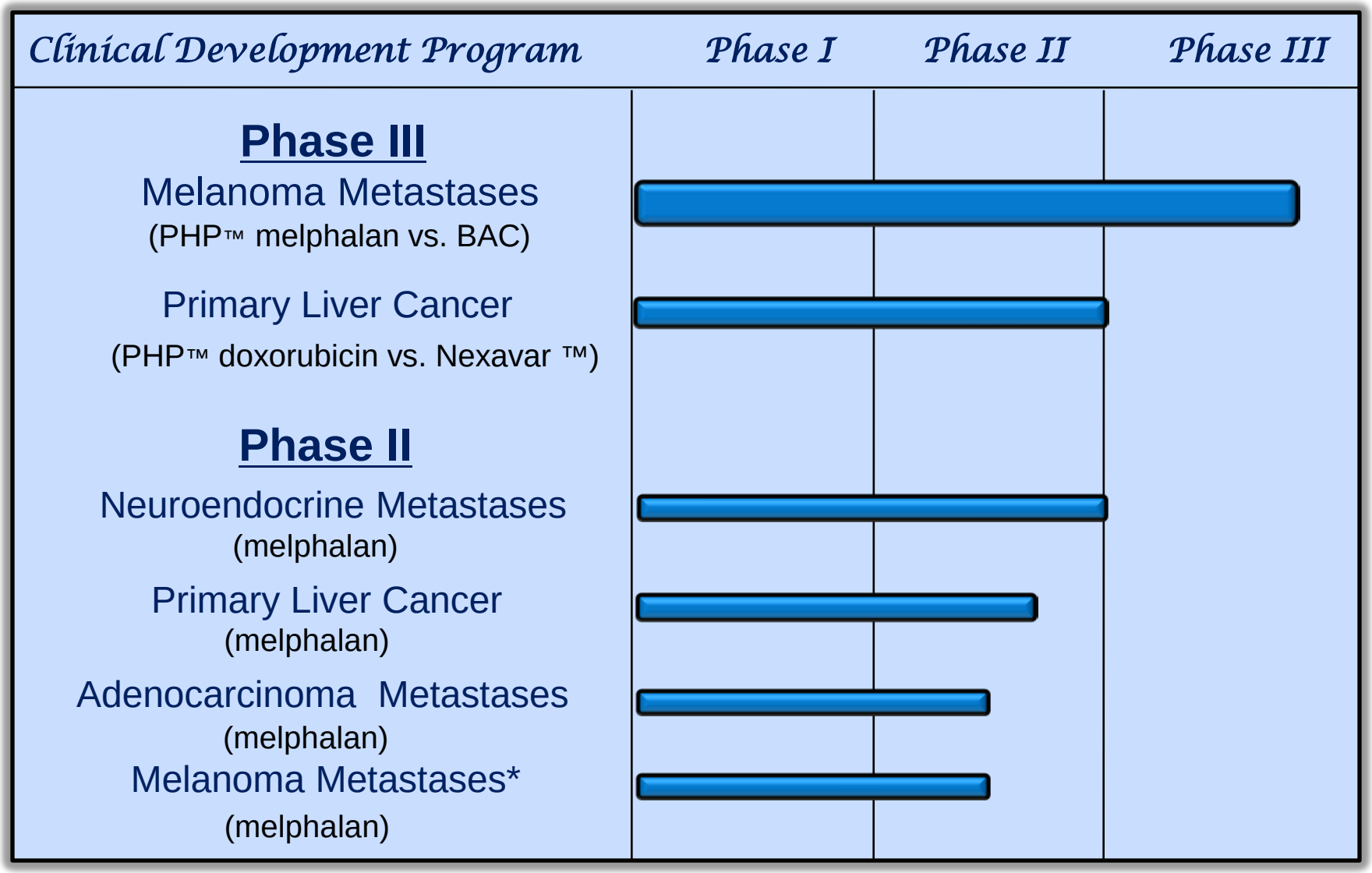
1. Cancer PPO, p. 335, 2005 2. Hepatogastro 50(54):1919-1926, 2003 3. Clin Can Res 9:6343-6349, 2003

The Delcath PHP System

Strengths

- PHP is a **non-surgical** and **repeatable** procedure
- Clinical studies have demonstrated very **compelling results**
- **Platform Technology -** other organs and body regions
- **Platform Technology** – other cancers and infectious diseases such as primary liver cancer (HCC), metastatic CRC, neuroendocrine mets and Hepatitis - HCV and HBV
- **Straightforward Regulatory Pathway** - Delcath has been granted 3 Orphan Drug designations and Special Protocol Assessment (SPA) by the FDA

Current Clinical Trials



*Patients who previously received surgical IHP, ineligible for Phase III melanoma trial

Clinical Trials

Metastatic Melanoma

Phase I Trial – Proof of Concept (2005)

Phase I Ocular Melanoma Patients

11 evaluable patients -

Response (duration in months):

PD	2
MR (14+, 9, 7)	3
PR (17, 15, 7+, 7)	**4**
CR (12, 11)	**2**
Objective Response Rate	**6 (55%)**
Overall Response Rate	9 (82%)

Safety Data – Phase I Trial (all patients)

- Maximum Dose – 3.5 mg/kg
- Grade IV toxicities observed
- **Optimal Dose – 3.0 mg/kg**
- Side effect profile similar to standard melphalan (.25mg/kg)
- Manageable hematological toxicities

Phase I Trial – Metastatic Melanoma

Radiographic Treatment Response (n=16)

Response	n	%	Duration
Overall	8	50	
Complete	2	13	10, 15
Partial	6	37.5	2+,8, 8, 12, 15, 16
Stable Disease	4	25	7, 7, 8, 8+
Progressive Disease	4	25	
Not Evaluable	2	13	(vascular anomaly)

Site of Disease Recurrence/Progression (n=12 responders)

Hepatic	6	50
Systemic	4	33
Both	2	17

+ censored with stable or responding hepatic disease with systemic progression

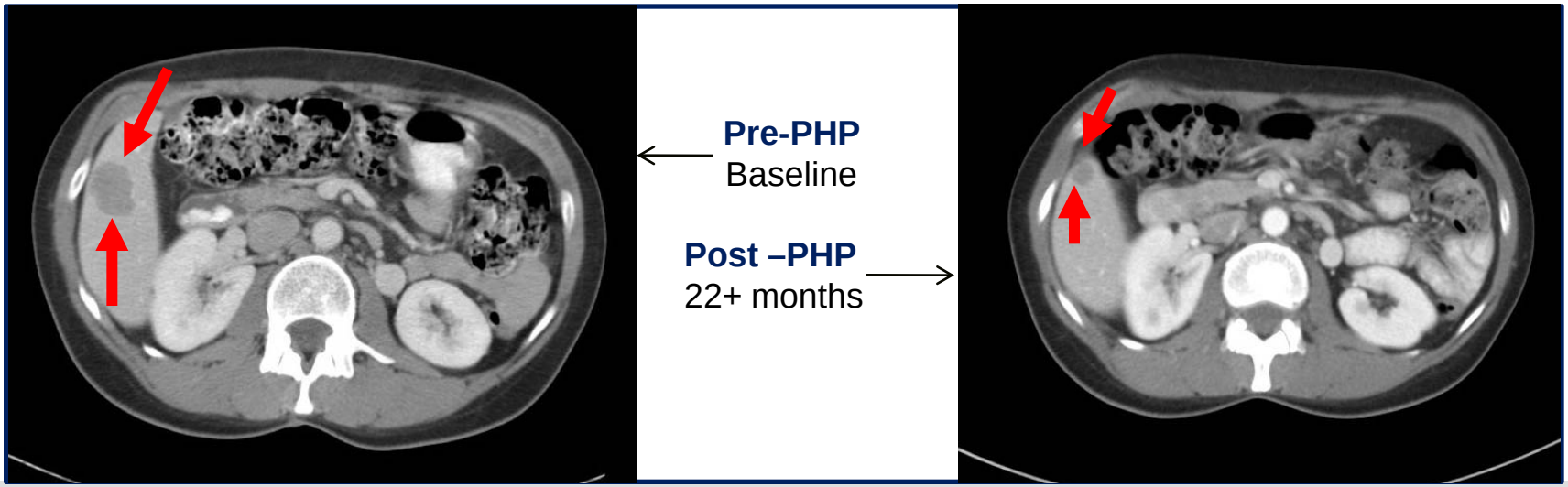
Phase III Trial – Metastatic Melanoma

Phase III Trial Design

- 92 patients - PHP™ vs. Best Alternative Care (BAC)
- Primary trial endpoint: Hepatic Progression Free Survival (PFS)
- Cross-over from BAC to PHP™ permitted after progression
- 80 patients enrolled as of August 10, 2009

Expected Hepatic PFS for Trial Success: 7.73 months (PHP™) vs. 4 months (BAC)

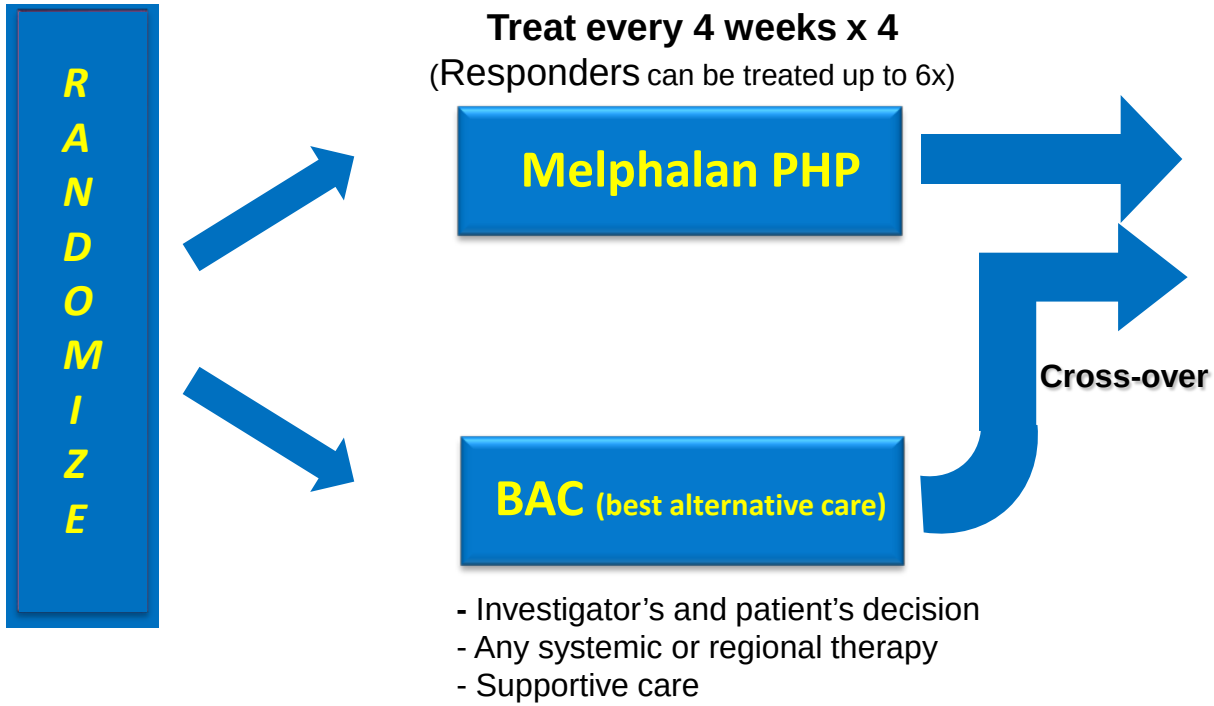
- Secondary Endpoints:
- (i) hepatic response and duration of hepatic response
- (ii) overall response and duration of overall response
- (iii) overall survival



Phase III Metastatic Melanoma Trial

92 patients

- Predominantly or liver-only metastatic ocular or cutaneous melanoma



- Trial fast-tracked and operating under Special Protocol Assessment (SPA) with FDA
- Primary trial endpoint: Hepatic Progression Free Survival (PFS)
- Cross-over from BAC to PHP™ permitted after progression
- Secondary endpoints: hepatic and overall response; overall survival

Expected Hepatic PFS for Trial Success: 7.73 months (PHP™) vs. 4 months (BAC)

Phase III – Metastatic Melanoma

- **Current Clinical Trial Centers:**
  - **National Cancer Institute – Bethesda**
  - University of Pittsburgh Medical Center – Pennsylvania
  - University of Maryland Medical Center – Maryland
  - Moffitt Cancer Center – Florida
  - University of Texas - Texas
  - John Wayne Cancer Institute - California
  - Swedish Medical Center – Colorado
  - Providence Health System – Oregon
  - Ohio State University - Ohio
  - St. Luke's Cancer Center - Pennsylvania
  - Albany Medical Center – New York
  - Atlantic Health System – New Jersey

Leading Clinical Investigators

Marybeth S. Hughes, M.D., F.A.C.S

Principal Investigator

Surgery Branch, National Cancer Institute, NIH

10 Center Drive Room 4W-5940, MSC 1201

Bethesda, MD 20892

Office: 301-594-9341

Office: 301-402-4396

hughesm@mail.nih.gov

James F. Pingpank, Jr., MD, FACS

Associate Professor of Surgery

Division of Surgical Oncology

Suite 406, UPMC Cancer Pavillion

5150 Centre Avenue

Pittsburgh, PA 15232

Office: 412-692-2852

Cell: 301-325-5733

Fax: 412-692-2520

Pingpankjf@upmc.edu

H. Richard Alexander, Jr., M.D. Associate Chair for Clinical Research

Department of Surgery

University of Maryland Medical Center

22 S. Greene St. S4B05A

Baltimore, MD 21201

Office: 410-328-3828

hralexander@smail.umaryland.edu

Assistant Member

Jonathan S. Zager, MD, FACS

Moffitt Cancer Center

Cutaneous Oncology and Sarcoma

Experimental Therapeutics

12902 Magnolia Drive

SRB 4. 24012

Tampa, Florida 33612

Office: 813-745-1085

Pager: 813-256-4661

jonathan.zager@moffitt.org

Phase I/II Clinical Trials

Metastatic Neuroendocrine Tumors

Phase I/II Trials – Neuroendocrine Tumors

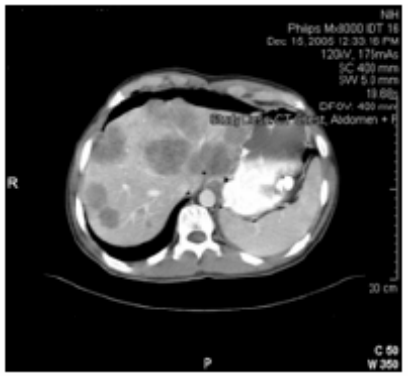
Neuroendocrine Tumors Trial Results (n=23*)

- **Primary Tumor Histology:**
  - Carcinoid 6
  - Pancreatic Islet Cell 17
- **Median Hepatic PFS:** 39
- **Overall survival after PHP™ :** 40
- **Response:**
  - NE (Tox**, Incomplete Tx, OLT) 4
  - PD 1
  - MR/SD 3

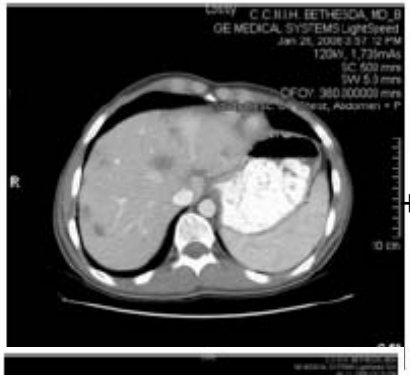
PR – (Partial Response - 30 to 99% tumor reduction) 13

CR – (Complete Response -no evidence of disease) 2

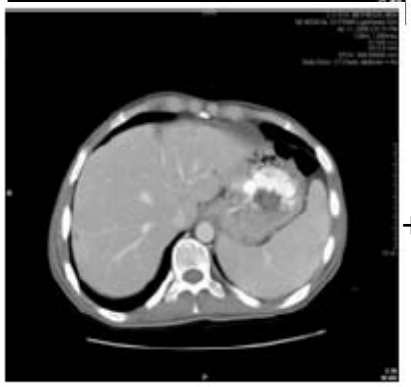
Objective Tumor Response - 15 (79%)



Pre-PHP: Baseline



Post-PHP#1: + 6 weeks

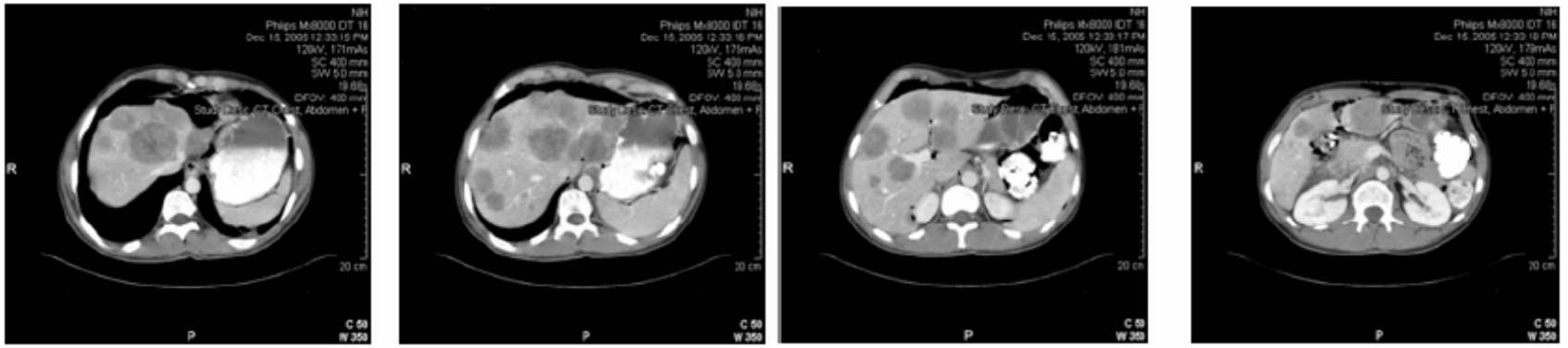


Post-PHP#2: +4 months

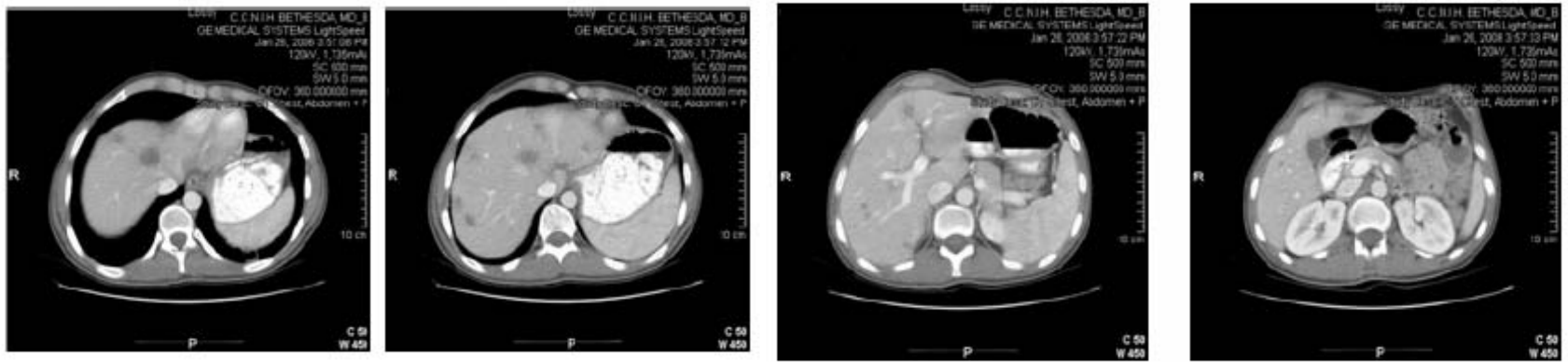
*NCI presentation 3/30/08 at AHPBA

**hypercalcemia, sclerotic hepatic art.

Metastatic Neuroendocrine Tumors

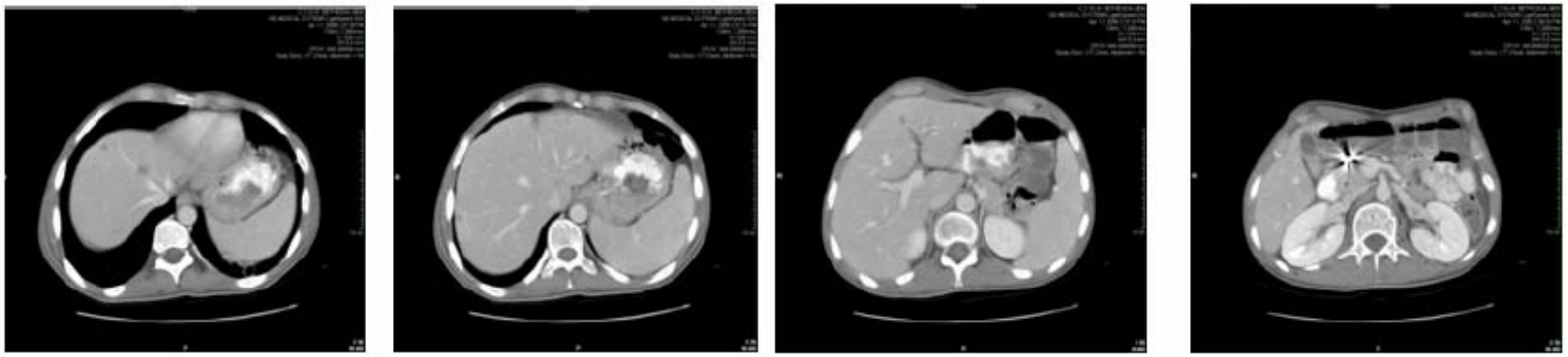


Pre-PHP: Baseline



Post-PHP#1:

+ 6 weeks



Post-PHP#2:

+4 months

Business Strategy – 3 LEGS

- **World Class Device Company**
  - Transition from developmental stage to operational stage
  - Manufacturing, sales, marketing OUS in 2010 and USA 2011
  - Complete trial enrollment 2009
  - Goal: Receive CE approval by mid 2010
  - Goal: Receive FDA approval by mid 2011

- **Pursue USA Pharma Partners** to co-develop and fund additional indications for Delcath system dramatically increasing market size for existing portfolio of chemotherapeutic agents and broaden PHP market

- **Pursue Asian Strategic Partners** to invest and develop markets for China, Korea, and Japan.

Business Strategy – Partnerships

- HEP – C/B Initiate testing of high dose interferon/anti-virals for HCV and HBV
- Primary liver cancer survival trial-doxorubicin vs. sorafenib
- CRC trials with melphalan delivered via PHP
- Neuroendocrine Phase II/III survival study with melphalan
- Develop systems for other organs, such as Kidney, Lung, Brain, Pelvis, and others

Strong Intellectual Property Protection

Patent Protection

- Seven US Patents and 20 foreign counterparts granted
- Primary device patent set to expire August 2016
- Portfolio protection extends through 2023 – portfolio includes use of the Delcath PHP System™ for glandular, organ and pelvic perfusion
- Pending patent applications before USPTO and foreign offices

FDA Protection

- Post FDA approval up to five-years of patent extension available
- PMA process secures three years of market exclusivity for PHP device
- Orphan Drug Designation granted for melphalan in the treatment of ocular melanoma, cutaneous melanoma and metastatic neuroendocrine tumors
- Additional Orphan Drug applications to be filed for other drugs and indications including HCC and CRC

Initial Markets

Disease	US Prevalence*	Predominant Liver Mets	Potential Revenue**
Cutaneous Melanoma	36,300	25%	**$ 340,312,500**
Ocular Melanoma	2,000	90%	**$ 67,500,000**
Hepatocellular Carcinoma	18,400	95%	**$ 655,500,000**
Neuroendocrine	26,900	33%	**$ 332,887,500**
Colorectal	194,000	40%	**$ 2,910,000,000**

* Stage IV Prevalence in US, except HCC which is annual deaths

** Assumes 2.5 PHP treatments per patient at an ASP of $15,000

Potential USA Market for Above Five Diseases - $ 4.3 Billion

Financial Position and Capitalization

- Ticker: **DCTH** (NASDAQ)
- Share Price: $3.16 (August 10, 2009)
- 52-Week Range: $0.82 – $4.11
- Cash: $8.9 million (June 30, 2009)
- Debt: None
- Burn Rate: Approximately $925,000/month
- Shares Out: 26.3 million (32.5 million* FD)
- Market Value: $83 million (August 10, 2009)

*Fully diluted includes an additional 2.37 million options at $3.37 and 3.85 million warrants at $3.62

Investment Considerations

- **Large Unmet Medical Need**
- **Proprietary Clinical Approach**
- **Strong Phase I/II Data**
- **Phase III Enrollment 85% Complete**
- **2010 OUS Revenue Potential**

Delcath Systems, Inc.

Advancing Targeted Drug Delivery

Investor Presentation
August 2009

www.delcath.com
www.livercancertrials.com
Nasdaq: DCTH