

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K/A**

**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): **January 10, 2011**

**DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-16133  
(Commission File Number)

06-1245881  
(IRS Employer  
Identification Number)

810 Seventh Avenue, Suite 3505, New York, New York, 10019  
(Address of principal executive offices, including zip code)

(212) 489-2100  
(Registrant's telephone number, including area code)

NONE  
(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 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

Item 9.01(d) of the form 8-K filed by Delcath Systems, Inc. on January 10, 2011 is hereby amended to replace Exhibit 99.1 with the corrected version thereof attached hereto.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Delcath Systems, Inc. Investor Presentation Slides

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DELCATH SYSTEMS, INC.

Dated: January 11, 2010

By:           /s/ Peter Graham            
Name: Peter Graham  
Title: Executive Vice President &  
       General Counsel

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## EXHIBIT INDEX

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99.1	Delcath Systems, Inc. Investor Presentation Slides



# Investor Presentation

## January 2011

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 which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements that are not historical facts. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including, the progress of our research and development programs and future clinical trials; acceptance of our New Drug Application by the FDA and approval thereof, acceptance of our CE mark Technical File by our Notified Body and approval thereof; our ability to successfully commercialize the Delcath Chemosaturation System in the United States and foreign markets and any corresponding revenue, our ability to enter into distribution and strategic alliances in the US and foreign markets and any corresponding revenue, the actions of regulatory authorities; our ability to obtain reimbursement coverage for the Chemosaturation System; overall economic conditions; the availability of capital; and other factors described in the section entitled “Risk Factors” in our most recent Annual Report on Form 10-K and the Quarterly Reports on Form 10-Q that we file with the Securities and Exchange Commission.**

# Company Highlights

- § Our mission is making established chemotherapeutic drugs work better in target organs
- § Chemosaturation delivers ultra-high dose chemotherapy to the liver, while complementing systemic cancer therapies
- § Minimally invasive approach to regional cancer therapy that combines well-established drug with catheter-based delivery and filtration system
- § Successful Phase III trial results reported
- § Filed NDA for orphan drug and delivery apparatus and CE Mark for device
- § Platform technology with potential use in multiple liver-based cancers, and other regions or organs
- § Large, unmet market opportunity: 2.6 million liver cancer patients worldwide
- § Issued patents, orphan drug designations present competitive barriers
- § Deep and experienced management team

Concentrating the Power of Chemotherapy

# Deep and Experienced Management Team

Executive	Title	Prior Affiliation(s)	Years of Experience
Eamonn Hobs	President and CEO	AngioDynamics, -Z-EM	30
David McDonald	CMO and EVP, R&D	AngioDynamics, RBC Capital Markets	28
Krishna Kandarpa, M.D., Ph.D.	CMO and EVP, R&D	Harvard, MIT, Cornell, UMass	37
Agustin Gago	EVP, Global Sales & Marketing	AngioDynamics, -Z-EM	29
Peter Graham	EVP & General Counsel	Bracco, -Z-EM	16
John J.D. Purpura	EVP, Regulatory Affairs & Quality Assurance	E-Z-EM, Sanofi-Aventis	27
Bill Appling	SVP Operations & Medical Device R&D	AngioDynamics	25
Bernie Tyrrell	SVP N. American Sales & Marketing	Epicept, Otsuka, Astra Zeneca, Johnson & Johnson, Eli Lilly	33
Dan Johnston, Ph.D.	VP, Pharma R&D	Pfizer, Wyeth	10

Significant Combination Product Approval and Commercialization Experience



# Recent Accomplishments

- § Built leadership team with deep pharmaceutical, device and commercialization experience
- § Established manufacturing facility
- § Reported successful Phase III Trial results
- § Signed long-term supply agreement with leading melphalan manufacturer
- § Raised over \$70 million in equity capital
- § Submitted for regulatory approvals in U.S. (NDA) and EU (Class III medical device)
- § Positioned for 2011 commercialization

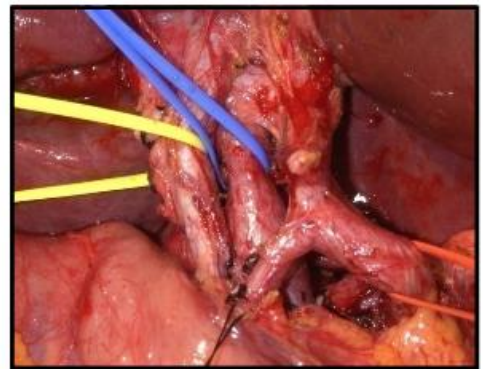
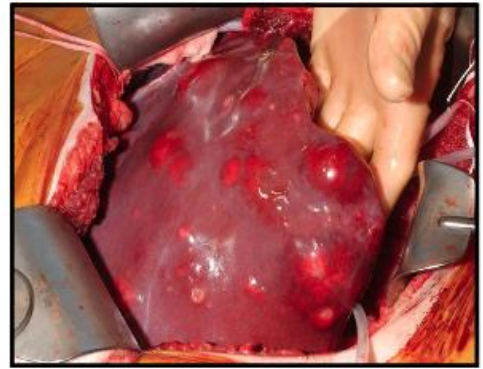
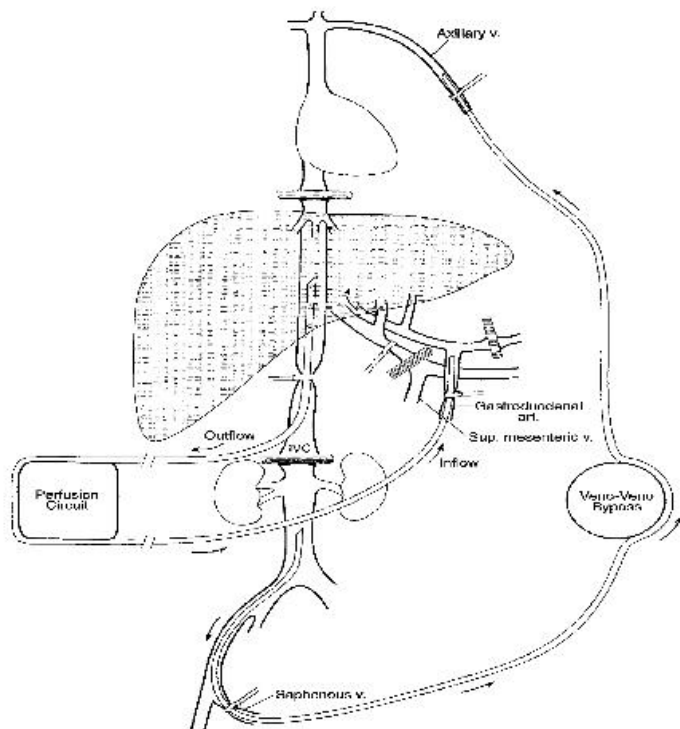
Executing on Sustainable Growth Strategy

# Spectrum of Liver Cancer Treatments

Type of Treatment	Advantages	Disadvantages
Systemic	<ul style="list-style-type: none"><li>ü Non-invasive</li><li>ü Repeatable</li></ul>	<ul style="list-style-type: none"><li>- Systemic toxicities</li><li>- Limited efficacy in liver</li></ul>
Regional (e.g., IHP)	<ul style="list-style-type: none"><li>ü Therapeutic effect</li><li>ü Targeted</li></ul>	<ul style="list-style-type: none"><li>- Invasive/limited repeatability</li><li>- Multiple treatments are required</li></ul>
Focal	<ul style="list-style-type: none"><li>ü Isolated removal of tumor</li></ul>	<ul style="list-style-type: none"><li>- 90% unresectable</li><li>- Invasive and/or limited repeatability</li></ul>

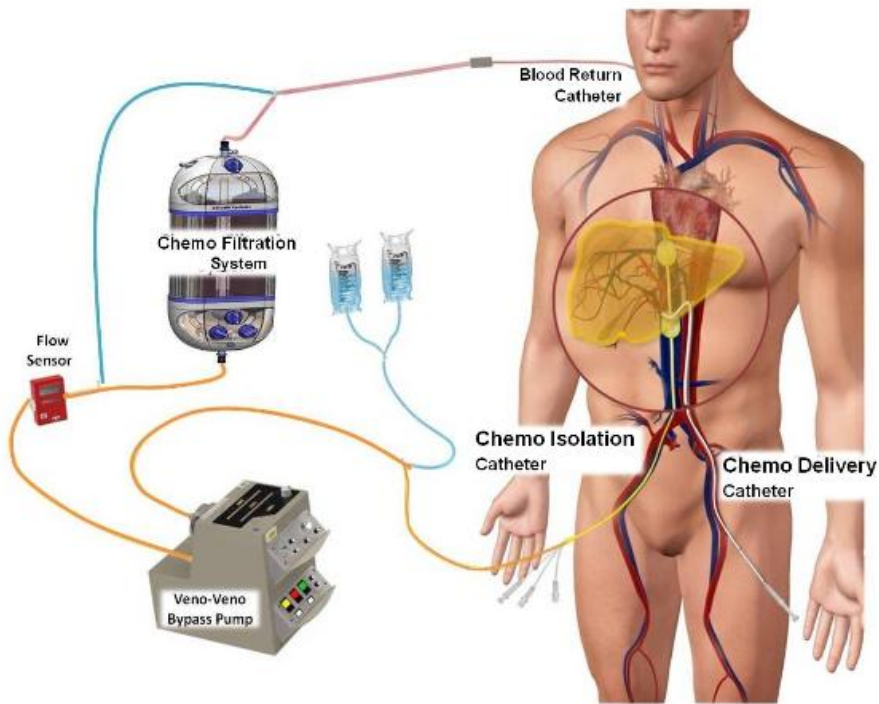
Existing Treatments Involve Significant Limitations

# Open Surgical IHP - Where It All Began



**IHP: Proof of Concept, but High Morbidity and Non-Repeatable**

# The Delcath Chemosaturation System



Note: Image not to scale.

## Advantages of Chemosaturation

### § ISOLATION

§ Treats entire liver

### § SATURATION

§ Allows for ~ 100x effective dose escalation of drug agents at tumor site

### § FILTRATION

§ Controls systemic toxicities

Converts Traumatic Open Surgery to Minimally Invasive, Repeatable Procedure

# Melphalan Dosing & Background

Type	Dosing (mg/kg)
Multiple Myeloma	0.25
(label) Chemoembolization	0.62
Surgical Isolated Hepatic Perfusion	1.50
(HEP) Myelablation	2.50-3.50
<b>Chemosaturation (PHP)</b>	<b>3.00</b>

- § Well understood, dose dependant, tumor preferential, alkylating cytotoxic agent that demonstrates no hepatic toxicity
- § Manageable systemic toxicities associated with Neutropenia and Cytopenia
- § Drug dosing over **10x higher** than FDA-approved dose via systemic IV chemotherapy
- § Dose delivered to tumor is approximately **100x higher** than that of systemic IV chemotherapy

A Great Drug For Liver Cancer Therapy

# What Chemosaturation Offers

## Patients:

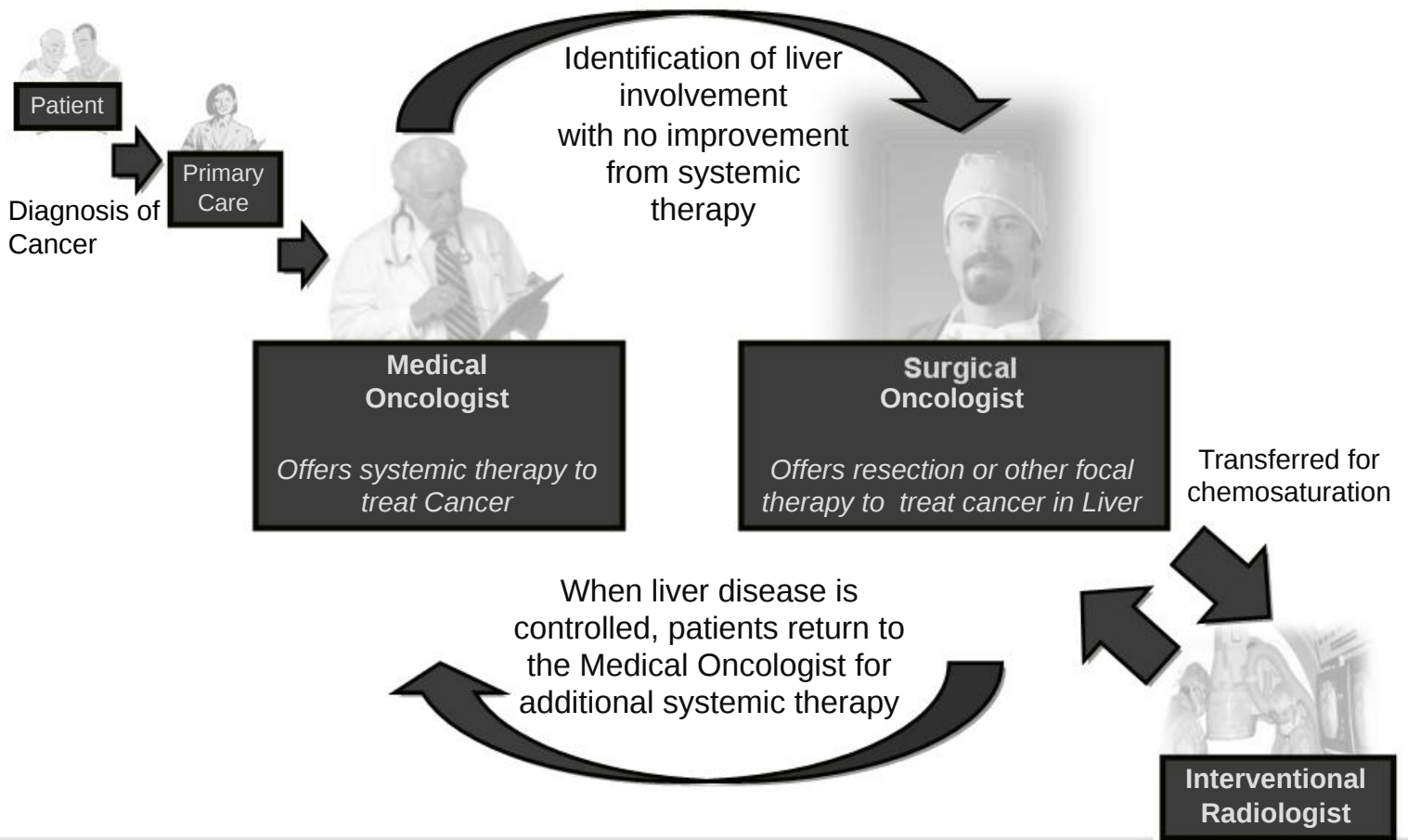
- Significant improvement in disease control in the liver compared to standard of care in patients with unresectable hepatic melanoma mets
- Manageable systemic toxicities
- Time, so that primary cancers can continue to be treated

## Physicians:

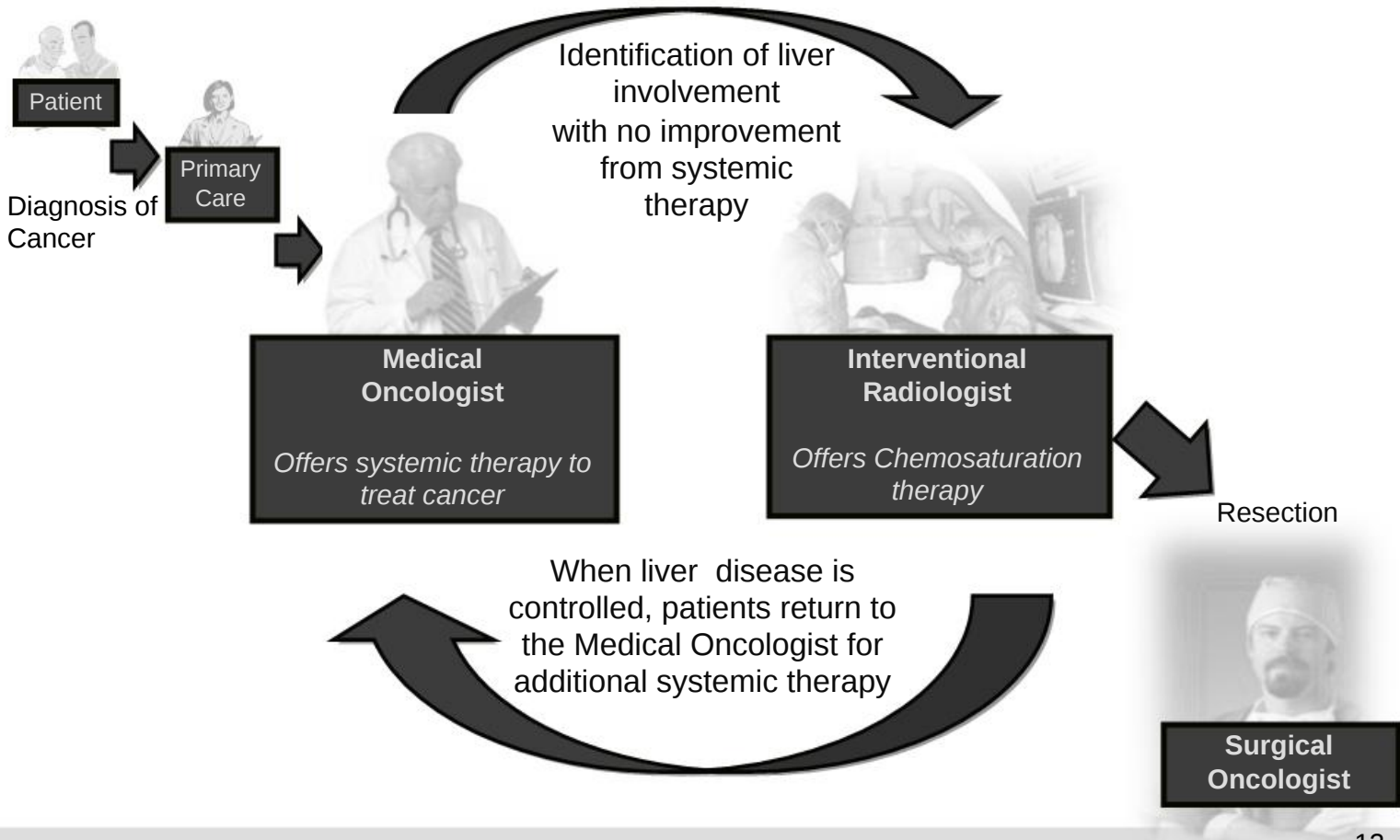
- Novel, targeted liver directed treatment to complement other cancer therapies
- Repeatable, percutaneous procedure
- Ability to treat the entire liver, including both visible and micro tumors
- Ability to continue treating patients for extra-hepatic disease

Attractive Clinical and Economic Proposition For Patient and Providers

# Current Patient Referral Path



# Future Patient Referral Path



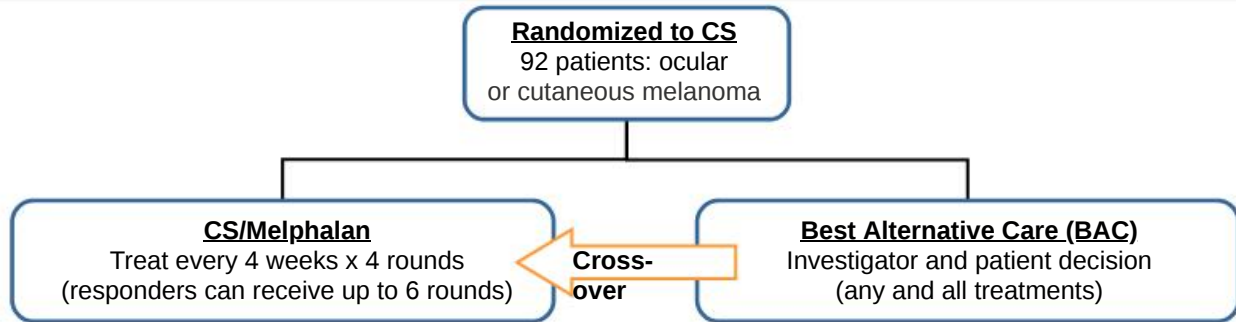


# Summary of Phase III Results

- § Primary endpoint exceeded
- § Secondary endpoints support results
- § OS cohort analysis - favorable
- § Safety profile - expected and in accordance with currently approved labeling for melphalan

Trial Outcomes Favorable and Consistent with Special Protocol Assessment

# Phase III Clinical Trial Design



## Primary Trial Endpoint

- § Statistically significant difference in Hepatic Progression Free Survival ("hPFS"): **p < 0.05**
- § Over 80% of Oncologic drugs approved by FDA between 2005 - 2007 on endpoints other than overall survival

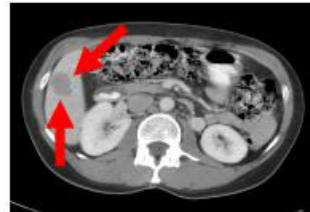
Modeled hPFS for Trial Success:

7.73 months (CS)  
vs.  
4 months (BAC)

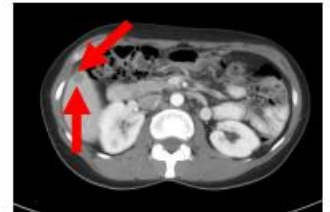
## Secondary Trial Endpoints

- § **Hepatic response** and duration of hepatic response
- § **Overall response** and duration of overall response
- § **Overall Survival - Diluted by Cross Over**
- § **SAP calls for analysis of various patient cohorts**

Hepatic Response - Metastatic Melanoma



**Pre-CS (Baseline)**



**Post-CS (22+ Months)**

Fully Powered, 93 Patient, Randomized, Multi-Center NCI Led Study

## 2010 ASCO Presentation of Phase III Clinical Trial Results

- § Trial results exceed primary endpoint expectations; p value = 0.001
- § Treatment arm shows 5x median hPFS compared to control arm
- § CS/PHP median hPFS of 245 days compared to 49 days for BAC
- § Hazard Ratio = .301
- § Patients failed prior therapies (radiation, chemo, immuno, image guided local)
- § 90% Ocular, 10% Cutaneous - No difference in response
- § Overall PFS 186 vs. 46 days for BAC
- § 34% response rate for CS/PHP compared to 2% for BAC
- § 52% stable disease for CS/PHP compared to 27% for BAC
- § 86% overall clinical benefit (CR + PR + SD)

**Strong Clinical Trial Results**

## 2010 ASCO Presentation of Phase III Clinical Trial (cont.)

- § Majority of BAC patients crossed over and obtained similar response from treatment
- § Total 93 patient trial - 10 months median OS vs. 4 months expected <sup>1</sup> (due to cross over provision, most patients received PHP/CS treatment)
- § OS cohort analysis - all positive trends
  - a) Median survival of 298 days for treatment arm compared to 124 in non-crossover BAC patients
  - b) Median survival of 398 days for BAC Cross Over patients vs. 124 non-cross over BAC patients
- § OS Secondary endpoint - No difference in Kaplan-Meier curves(due to cross over treatment response)
- § Safety profile as expected - in line with current FDA approved labeling for IV administration of Melphalan and Phase I CS/PHP study results
  - a) Treatment related Deaths:
    - § 3/40 patients (7.5%) 3/116 procedures (2.6%)
    - § Neutropenic Sepsis (n=2) 5%, Hepatic Failure (n=1) 2.5% (95% tumor burden)
    - § Current approved labeling for Melphalan - 3% to 10% mortality rate.
  - b) Instituting REMS (Risk Evaluation & Mitigation Strategy) to address proper management associated with safe use.

<sup>1</sup> Source: Unger et. al. Cancer 2001;91: 1148

**Encouraging Survival Data With Expected Safety Profile**

# Phase I/II NCI Trials - Neuroendocrine

## Neuroendocrine Tumor Trial Results (n=23)\*

	Number (n)
<b>Primary Tumor Histology</b>	
Carcinoid	3
Pancreatic Islet Cell	17
<b>Response</b>	
Not Evaluable (Toxicity, Incomplete treatment, Orthotopic Liver Transplantation)	4
Progressive Disease	1
Minor Response / Stable Disease	3
<b>Partial Response (30.0% - 99.0% Tumor Reduction)</b>	<b>13</b>
<b>Complete Response (No Evidence of Disease)</b>	<b>2</b>
<b>Objective Tumor Response</b>	<b>15</b>
<i>Objective Tumor Response Rate</i>	<i>79%</i>
<b>Duration (months)</b>	
Median Hepatic	39
BFS	
Overall Survival After CS	40



Pre-CS  
(Baseline)

Post-CS #1  
(+6 Weeks)

Post-CS #2  
(+4 Months)

\*Presentation at American Hepato-Pancreo-Biliary Association 2008 annual meeting

Promising Initial Response Rate in Attractive Market

# Product Development Pipeline

	Initial Opportunity	Near Term (< 5 years)	Intermediate Term (> 5 years)
U S	<ul style="list-style-type: none"> <li>Melanoma liver mets</li> <li>Drug-melphalan &amp; apparatus</li> </ul>	<ul style="list-style-type: none"> <li>Broaden label</li> <li>Other liver cancers - melphalan</li> <li>Apparatus improvements</li> </ul>	<ul style="list-style-type: none"> <li>Additional drugs</li> <li>Other organs</li> </ul>
E U	<ul style="list-style-type: none"> <li>All liver cancers - melphalan</li> <li>Class III device</li> <li>3<sup>rd</sup> party melphalan</li> </ul>	<ul style="list-style-type: none"> <li>Proprietary melphalan drug approval</li> <li>Apparatus improvements</li> </ul>	<ul style="list-style-type: none"> <li>Additional drugs</li> <li>Other organs</li> </ul>
A S I A		<ul style="list-style-type: none"> <li>Primary liver cancer (HCC)</li> <li>Drug-melphalan &amp; apparatus</li> </ul>	<ul style="list-style-type: none"> <li>Broaden label</li> <li>Other liver cancers - melphalan</li> <li>Additional drugs</li> <li>Other organs</li> </ul>

**Robust Development Program Planned**

# Intellectual Property

## Patent Protection

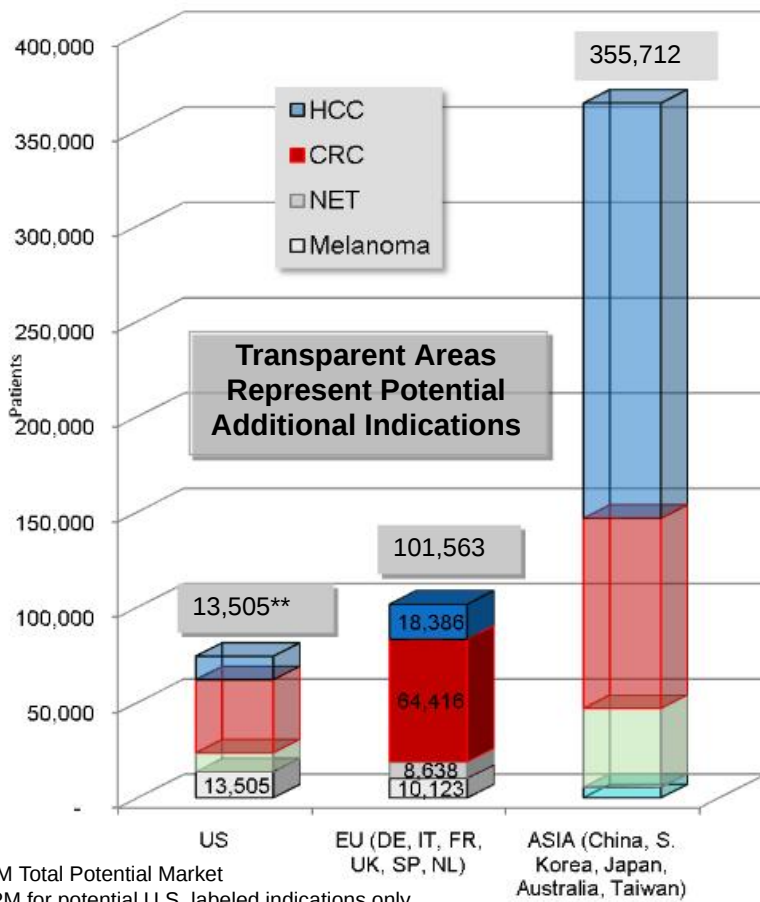
- § 7 issued U.S. patents, 10 foreign patents issued and 4 pending
- § Primary device patent set to expire August 2016
- § Post FDA approval up to 5 years of patent extension possible

## FDA Protection

- § Orphan Drug Designation granted for melphalan in the treatment of ocular melanoma, cutaneous melanoma and metastatic neuroendocrine tumors, as well as for doxorubicin in the treatment of HCC
- § Additional Orphan Drug applications to be filed for other drugs and indications, including HCC and CRC

Multiple Levels of Protection

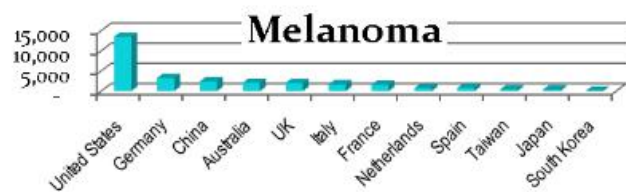
# Market Opportunity\* by Geography (patients)



- Initial indication for Melanoma liver mets in USA
- General indication in EU for delivery of melphalan to the liver permits physician use on a broad range of liver cancers
- Asia potentially requires long term clinical development pathway
- Australia- Niche opportunity (high melanoma incidence) - device approval following EU CE Mark
- Significant potential label expansion opportunity

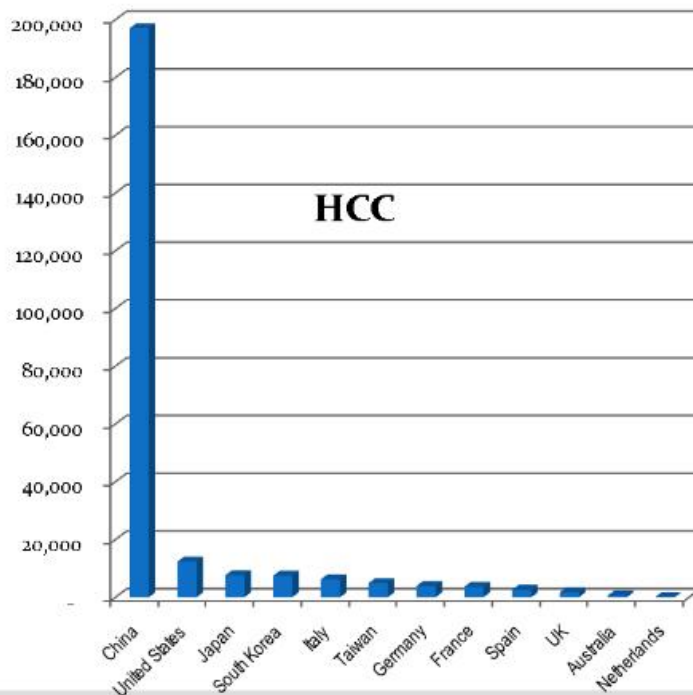
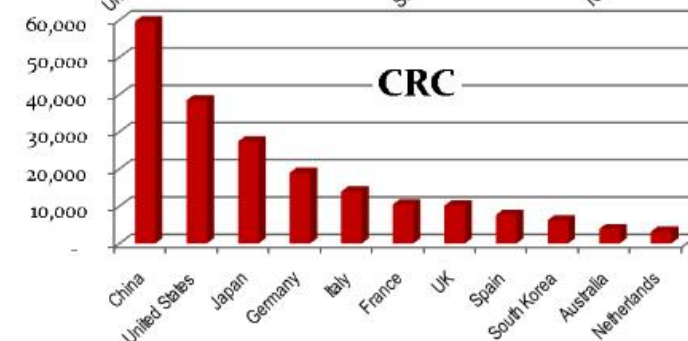
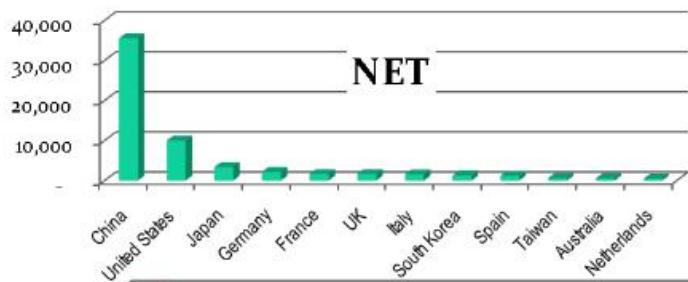


# Market Opportunity\* by Disease (patients)



Patients

- US - largest opportunity for Melanoma
- China - largest opportunity for HCC
- CRC - largest opportunity worldwide



\*TPM Total Potential Market

# Market by Disease\* - USA

<b>Liver Metastasis</b>	<b>Potential Market # Patients</b>	<b>Potential Market # Procedures (Avg 2.5/patient)</b>	<b>Potential Market (\$MM) \$20K ASP **</b>
Ocular Melanoma	1,622	4,055	\$81.1
Cutaneous Melanoma	11,883	29,708	\$594.2
<b>TOTAL MELANOMA (Initial Expected Label)</b>	<b>13,505</b>	<b>33,763</b>	<b>\$675.3</b>
CRC	38,423	96,057	\$1,921.1
HCC (Primary)	12,386	30,964	\$619.3
NET	9,986	24,965	\$499.3
<b>TOTAL OTHER (Potential Label Expansion)</b>	<b>60,794</b>	<b>151,985</b>	<b>\$3,039.7</b>

\*TPM Total Potential Market

\*\* Estimated ASP

# EU - Landscape

Initial Target Markets (DE, UK, FR, IT, SP, NL)

§ **CE Mark approval in EU-covers 29 countries**

§ **14 Countries currently have Melphalan for injection commercially available**

§ Belgium (BE), Czech Republic (CZ), Germany (DE), Estonia (EE), Spain (ES), France (FR), Ireland (IE), Italy (IT), Lithuania (LT), Luxembourg (LU), Netherlands (NL), Sweden (SE), Slovakia (SK), United Kingdom (UK).

§ **6 initial target countries (DE, UK, FR, IT, SP, NL) represent 89% of total potential market**

# Market by Disease - EU Device Only

Initial Target Markets (DE, UK, FR, IT, SP, NL)

	Germany (Direct)	UK (Direct)	France (Indirect)	Italy (Indirect)	Spain (Indirect)	Netherlands (Direct)	Total Potential (patients)	Potential Market (\$ millions) <sup>1,2,3</sup>
<b>Total Potential Market #Patients</b>								
Ocular Melanoma	403	296	294	284	197	79	1,553	\$46.6
Cutaneous Melanoma	2,834	1,735	1,314	1,398	628	662	8,571	\$257.1
CRC	18,978	10,155	10,490	13,952	7,694	3,151	64,420	\$1,932.6
HCC (Primary)	3,941	1,734	3,645	6,253	2,616	197	18,386	\$551.6
NET	2,168	1,624	1,645	1,579	1,185	438	8,639	\$259.2
<b>TOTAL</b>	<b>25,087</b>	<b>13,513</b>	<b>15,780</b>	<b>21,784</b>	<b>11,495</b>	<b>3,786</b>	<b>91,445</b>	<b>\$3,047.1</b>

1. Assumes 2.5 treatments per patient
2. Assumes ASP of \$12K (device only)
3. Assumes mix of direct sales and distributors

**Europe is Potential \$3.0 Billion Market Opportunity for Device Only**

# Market by Disease - EU

Initial Target Markets (DE, UK, FR, IT, SP, NL)

	Germany (Direct)	UK (Direct)	France (Indirect)	Italy (Indirect)	Spain (Indirect)	Netherlands (Direct)	Total Potential (patients)	Potential Market (\$ millions) <sup>1,2,3</sup>
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## Total Potential Market #Patients

Ocular Melanoma	403	296	294	284	197	79	1,553	\$62.1
Cutaneous Melanoma	2,834	1,735	1,314	1,398	628	662	8,571	\$342.8
CRC	18,978	10,155	10,490	13,952	7,694	3,151	64,420	\$2,576.8
HCC (Primary)	3,941	1,734	3,645	6,253	2,616	197	18,386	\$735.5
NET	2,168	1,624	1,645	1,579	1,185	438	8,639	\$345.6
<b>TOTAL</b>	<b>25,087</b>	<b>13,513</b>	<b>15,780</b>	<b>21,784</b>	<b>11,495</b>	<b>3,786</b>	<b>91,445</b>	<b>\$4,062.8</b>

1. Assumes 2.5 treatments per patient
2. Assumes ASP of \$16K, when Delcath branded melphalan is available
3. Assumes mix of direct sales and distributors

**Europe Represents Potential \$4.1 Billion Market Opportunity**

# Market by Disease - Asia

Initial Target Markets (China, Japan, S. Korea, Taiwan, Australia)

	China (Drug)	S. Korea (Drug)	Japan (Device)	Taiwan (Drug)	Australia (Device)	Total Potential (patients)	Potential Market <sup>1,2,3,4</sup>
<b>Total Potential Market # Patients</b>							
HCC (Primary)	197,082	7,486	7,625	4,945	604	217,742	\$4,899.2
<b>OTHER</b>							
CRC	59,644	6,219	27,396	2,762	3,891	99,912	\$2,248.0
NET	35,503	1,275	3,355	608	562	41,303	\$929.3
Ocular Melanoma	1,760	66	175	31	96	2,128	\$47.9
Cutaneous Melanoma	667	74	238	429	1,996	3,404	\$76.6
<b>OTHER TOTAL</b>	<b>292,229</b>	<b>14,980</b>	<b>38,376</b>	<b>8,315</b>	<b>5,057</b>	<b>358,957</b>	<b>\$8,201.0</b>

1. Assumes 2.5 treatments per patient
2. Assumes ASP of \$9K
3. Assumes mix of systems with and without Delcath branded melphalan
4. Assumes sales by distributors

**Asia Represents Potential \$8.2 Billion Market Opportunity**

# Three-Pronged Business Strategy

## Commercialization

- § Gain regulatory approval
  - Goal: receive CE approval for Class III device mid 2011
  - Goal: receive FDA approval for drug and delivery system mid 2011
  - Goal: receive EU approval for proprietary drug 2014
- § Build out direct specialty sales force for U.S.
- § Direct and Distribution partners OUS

## Pursue Asian Strategic Alliances

- § Chi-Fu Trading Company Ltd. signed 2/9/2010 for Taiwan
- § Proprietary drug and delivery apparatus approval for HCC

## Establish U.S. and EU Pharma Alliances

- § Co-develop and fund additional indications for Delcath Chemosaturation System™

Direct Sales Model, Complemented by Partnerships & Distributors

# Reimbursement Strategy

- Have retained leading reimbursement consultants
- Seek chemosaturtion specific codes in U.S.:
  - Physician:**
    - § While undergoing FDA review, apply for CPT Category III code
    - § Convert the Category III code to Category I following FDA approval
  - Hospital:**
    - § Apply for new ICD-9/10 procedure code to capture full procedure of hepatic isolation and chemosaturtion
    - § Request new DRG based on costs above those of existing DRGs and clinical dissimilarity to other hepatic procedures in current DRGs
- Europe: developing plans for initial focus countries

Reimbursement is a Multi-Faceted Work in Progress



# **Financials**

# Financial Summary

## Financial & Operating Overview

§ <b>Follow On Offerings:</b>	Raised ~ \$70 million in last twelve months
§ <b>Burn Rate:</b>	Approximately \$2.2 million/month
§ <b>Cash:</b>	~ \$54.1 million at September 31, 2010
§ <b>Debt:</b>	None
§ <b>Shares Out:</b>	42.8 million (49.4 million fully diluted*)
§ <b>Institutional Ownership:</b>	~ 21% at September 30, 2010
§ <b>Market Capitalization:</b>	~ \$419 million as of December 31, 2010
§ <b>Avg. Daily Volume</b> (3 mos)	~ 1.2 million

### Capital Structure Strengthened Significantly in 2010

\* As of September 30, 2010 Fully diluted includes an additional 3.8 million options at \$4.78, 2.70 million warrants at \$3.52, and 232,910 unvested restricted shares.

# Potential 2011 Milestones

## Regulatory

- FDA acceptance of NDA; PDUFA date established
- CE Mark approval
- NDA approval

## Publication

- Phase 3 metastatic melanoma to the liver
- Phase 2 metastatic neuroendocrine (NET) to the liver

## Clinical

- Phase 2 top line data release
- Presentation of Phase 2 data
- HCC development plan in Taiwan/Asia
- US label expansion plans and proposed studies

## Commercial

- Initial US commercialization
- Initial EU commercialization

Significant Value Creation Expected in 2011

# Company Highlights

- § Our mission is making well-established chemotherapeutic drugs work better in target organs
- § Chemosaturation delivers ultra-high dose chemotherapy to the liver, while complementing systemic cancer therapies
- § Minimally invasive approach to regional cancer therapy that combines well-established drug with catheter-based delivery and filtration system
- § Successful Phase III trial results reported
- § Filed NDA for orphan drug and delivery apparatus and CE Mark for device
- § Platform technology with potential use in multiple liver-based cancers, and other regions or organs
- § Large, unmet market opportunity: 2.6 million liver cancer patients worldwide
- § Issued patents, orphan drug designations present competitive barriers
- § Deep and experienced management team

Concentrating the Power of Chemotherapy

# Appendix I. - Delcath Sources for Market Estimates

American Cancer Society. Cancer Facts & Figures 2010. Atlanta: American Cancer Society; 2010.

Alexander, Richard H., David L. Bartlett, and Steven K. Libutti. "Current Status of Isolated Hepatic Perfusion With or Without Tumor Necrosis Factor for the Treatment of Unresectable Cancers Confined to the Liver." *The Oncologist* 5 (2000): 416-24.

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# Investor Presentation

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