

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

**FORM 8-K**

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

Date of report (Date of earliest event reported): **August 9, 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 7.01. Regulation FD Disclosure.**

A copy of Delcath Systems, Inc.'s updated investor presentation slides that the Company intends to use effective immediately is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The information disclosed under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

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**Item 9.01. Financial Statements and Exhibits.**

The following exhibit is filed herewith:

(d) Exhibits.

<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.

Dated: August 9, 2011

DELCATH SYSTEMS, INC.

By: /s/ Peter J. Graham

Name: Peter J. Graham

Title: Executive Vice President, General Counsel

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## EXHIBIT INDEX

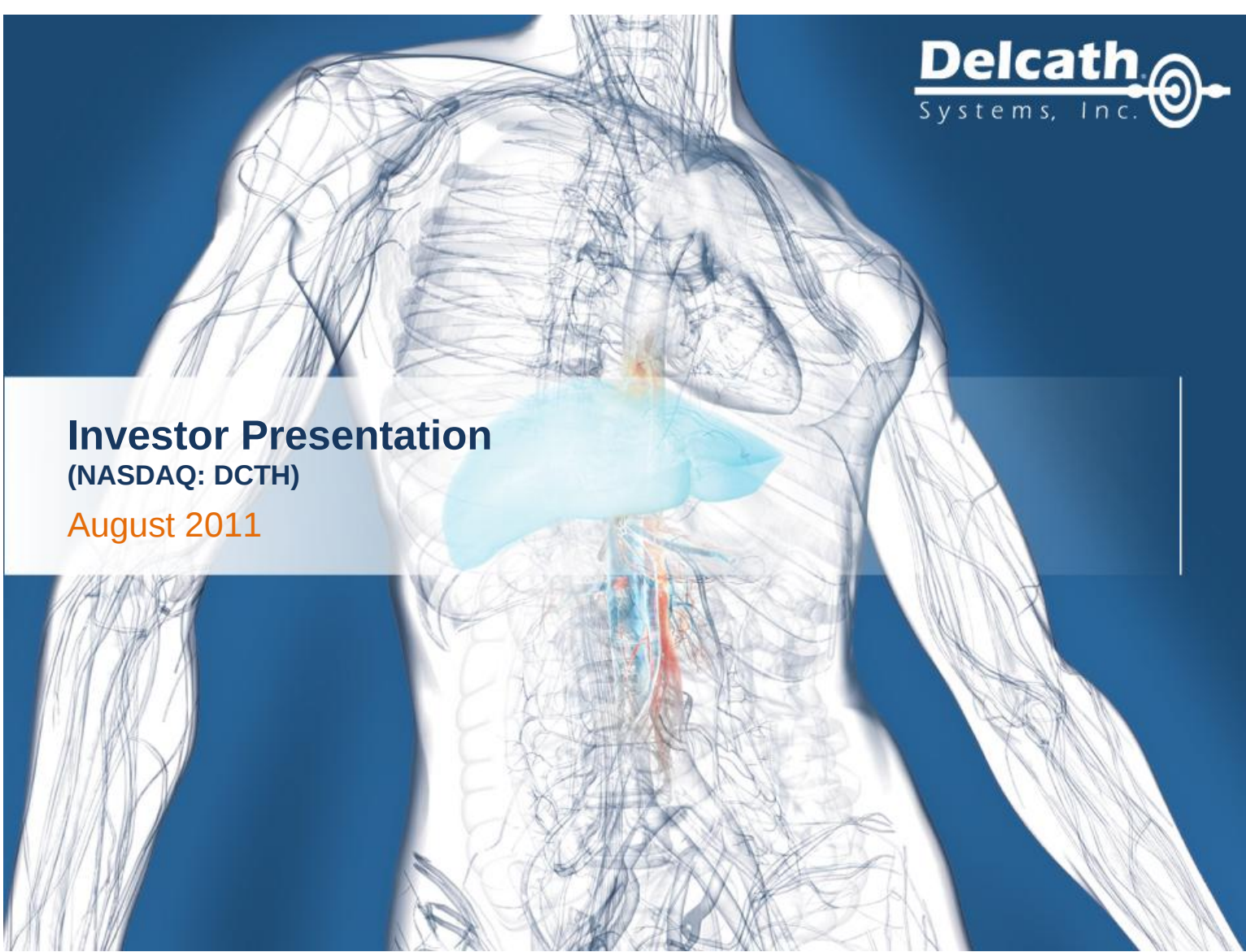
<b>Exhibit No.</b>	<b>Description</b>
99.1	Delcath Systems, Inc. Investor Presentation Slides

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# Investor Presentation

(NASDAQ: DCTH)

August 2011



# 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; uncertainties relating to the time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales, if any, for the chemosaturation delivery system in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the system as a treatment for patients with cancer in the liver, availability of melphalan in the EEA, acceptability of the Phase III clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from the FDA and the timing of our re-submission of our NDA, re-submission and acceptance of the Company's NDA by the FDA, approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, approval of the current or future chemosaturation system for other indications or the same indication in other foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, our ability to secure reimbursement for the chemosaturation system, progress of our research and development programs and future clinical trials, uncertainties regarding our ability to obtain financial and other resources for any research, development and commercialization activities, overall economic conditions 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

- Making established chemotherapeutic drugs work better in target organs
- Initial focus is high dose chemotherapy for improved disease control in the liver
- Successful and highly statistically significant Phase III trial results reported
- Received CE Mark approval for Class III medical device on April 13, 2011
- Positioned to address potential \$3.0 billion European labeled market opportunity
- Objective is to re-file 505(b)(2) NDA to FDA for orphan drug and delivery apparatus by end of 2011
- Potential \$675 million US labeled market opportunity
- Issued patents and orphan drug designations create competitive barriers
- Deep and experienced management team

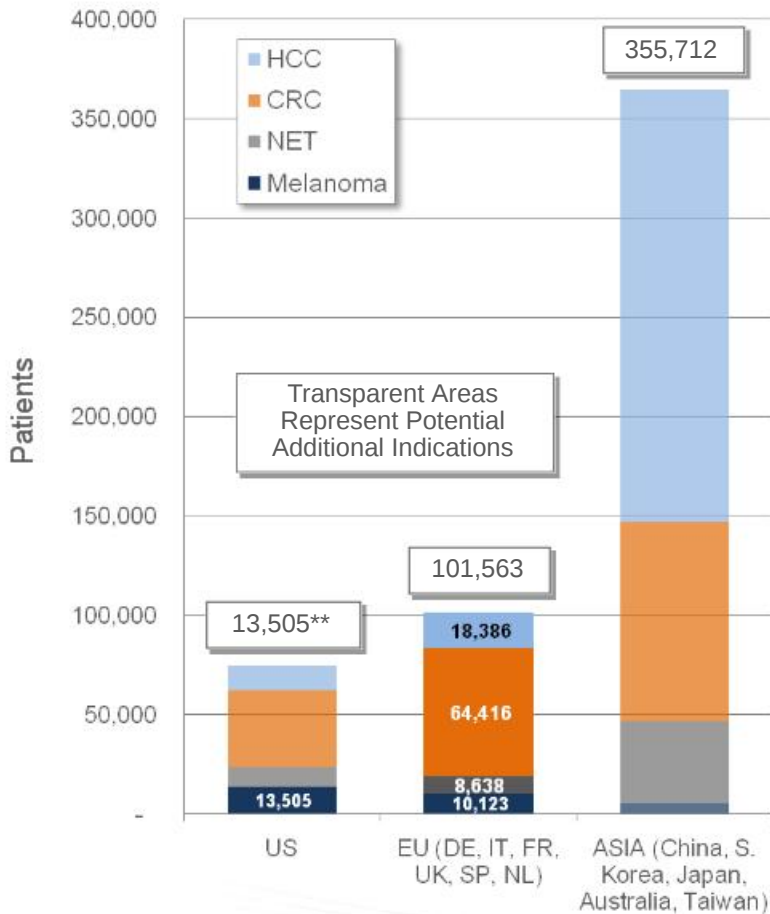
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Concentrating the Power of Chemotherapy to Improve Disease Control in the Liver

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# Potential \$3.75 Billion Labeled Market Opportunity\*



- CE Mark in EU for delivery of melphalan to the liver permits physician use on a broad range of liver cancers
- Potential \$3 Billion Long term EU Market Opportunity\*
- Leverage CE Mark to gain regulatory approvals in Asia, America's (EX US), MEA, and Australia
- Potential \$8 Billion Asia/Australia Market Opportunity\*
- Seeking initial indication for melanoma mets in U.S., a potential \$670 million \*\* market opportunity
- Significant potential label expansion possible is U.S. with additional studies

\*TPM Total Potential Market

\*\*TPM for initial U.S. labeled indication only

# Spectrum of Liver Cancer Treatments

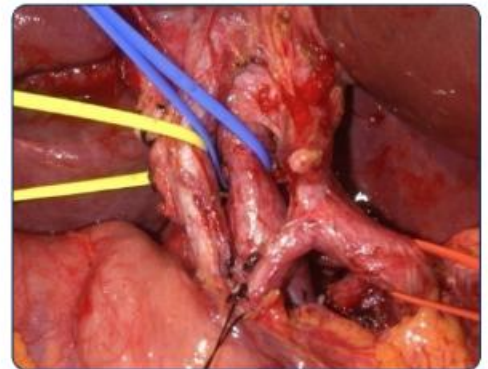
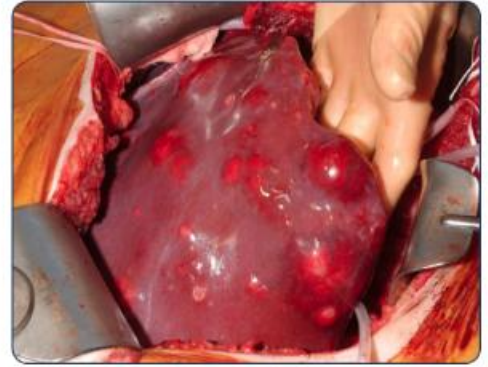
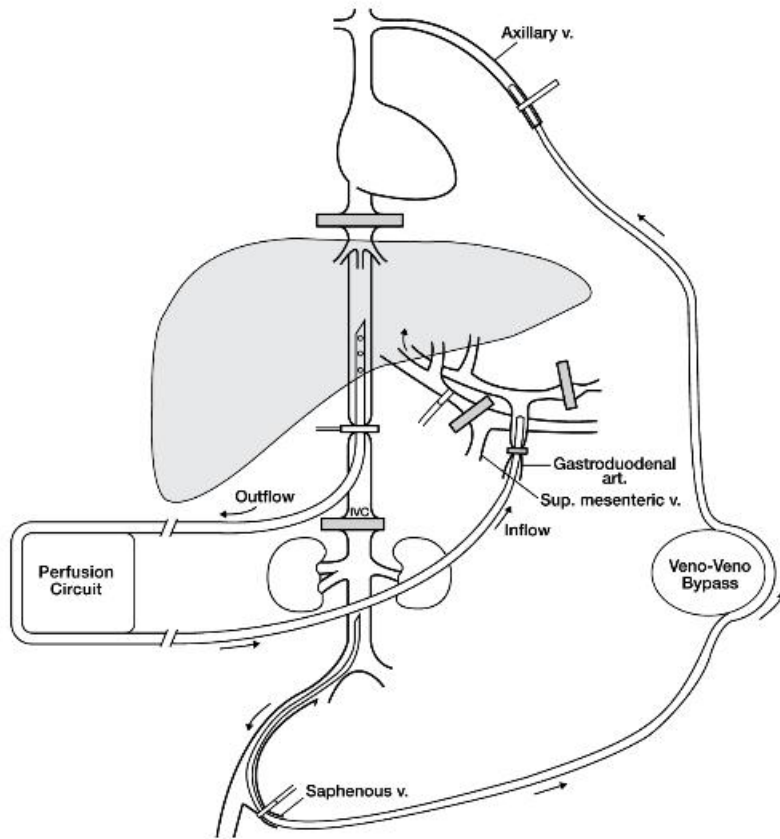
Type of Treatment	Advantages	Disadvantages
Systemic	<ul style="list-style-type: none"><li>o Non-invasive</li><li>o Repeatable</li></ul>	<ul style="list-style-type: none"><li>– Systemic toxicities</li><li>– Limited efficacy in liver</li></ul>
Regional (e.g., IHP)	<ul style="list-style-type: none"><li>o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

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Existing Treatments Involve Significant Limitations

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# Open Surgical IHP - Where It All Began



Isolated Hepatic Perfusion: Proof of Concept, but High Morbidity and Non-Repeatable



# Melphalan Dosing & Background

Type	Dosing (mg/kg)
Multiple Myeloma (label)	0.25
Chemoembolization	0.62
Surgical Isolated Hepatic Perfusion (IHP)	1.50
Myeloablation	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

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A Promising Drug For Liver Cancer Therapy

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# What Chemosaturation Offers

## Patients:

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

## Physicians:

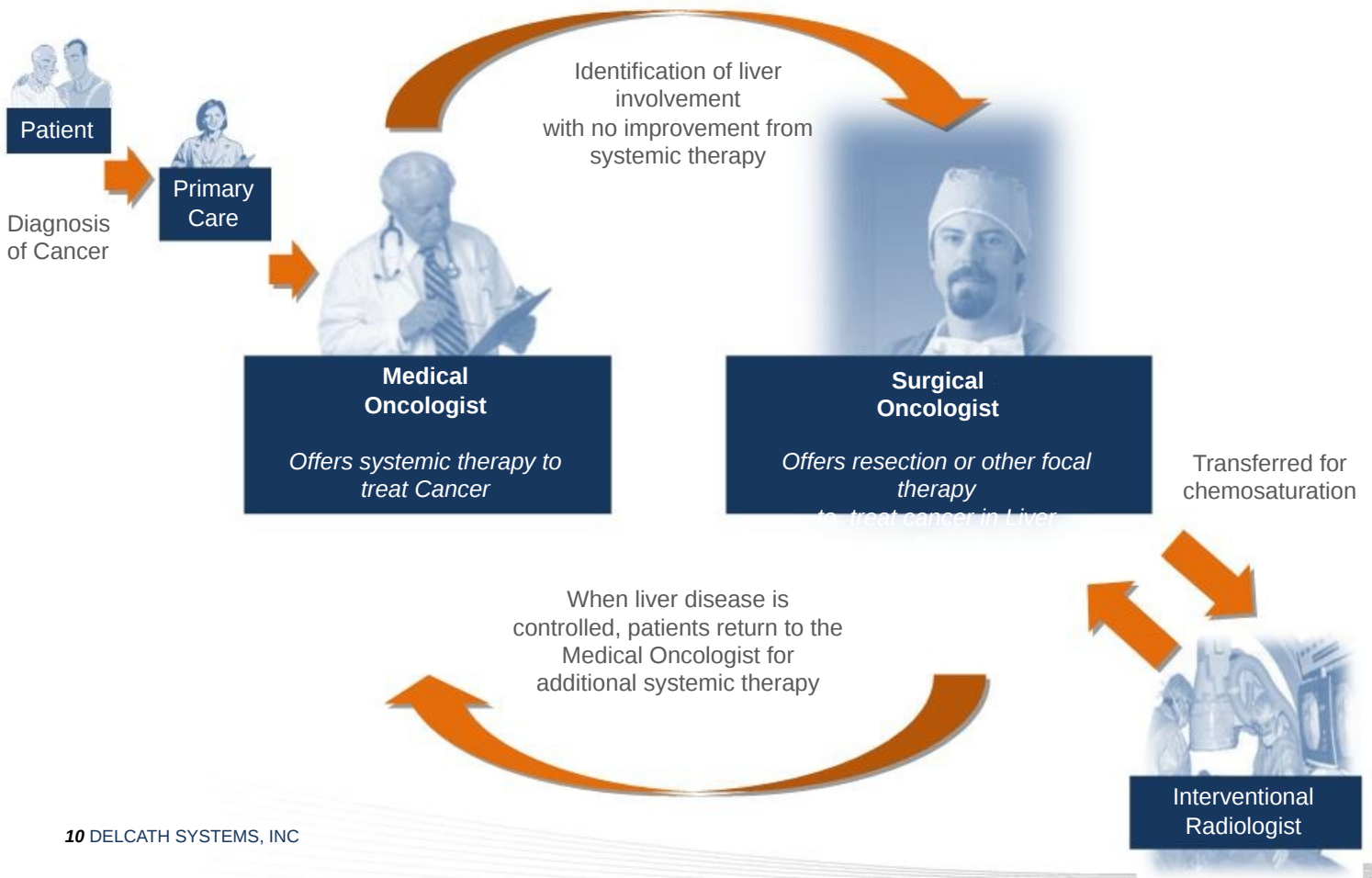
- o Novel, targeted liver directed treatment to complement other cancer therapies
- o Repeatable, percutaneous procedure
- o Ability to treat the entire liver, including both visible and micro tumors
- o Ability to continue treating patients for extra-hepatic disease

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Attractive Clinical and Economic Proposition For Patient and Providers

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# Current Patient Referral Path



# Summary of Phase III Results

- **Primary endpoint exceeded, p value = 0.001, hazard ratio of .301**
  - Treatment arm shows 5x median hepatic progression free (hPFS) survival compared to control arm
  - CS/PHP median hPFS of 245 days compared to 49 days for BAC
  - 86% overall clinical benefit (CR + PR + SD)
- **Secondary endpoints support results**
  - OS Secondary endpoint - No difference in Kaplan-Meier curves due to cross over treatment response (298 days compared to 301 days)
- **OS cohort analysis favorable**
  - Median survival of 298 days for treatment arm compared to 124 in non-crossover BAC patients
  - 14 treatment patients (6 treatment, 8 crossover) and 3 BAC patients still alive at 12/31/2010
- **Safety profile - expected and consistent with currently approved labeling for melphalan**
  - 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)

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**Trial Outcomes Favorable and Consistent with Special Protocol Assessment**

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# 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>
<b>Objective Tumor Response Rate</b>	<b>79%</b>
	<b>Duration (months)</b>
Median Hepatic PFS	39
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**

# High Efficiency (HE) Filter Media Development

## ***STATUS:***

- o Melphalan - Achieved consistent in-vitro first pass removal efficiency of 98% or better
- o Internal development project
- o Developed trade secret manufacturing process to create new filter medium

## ***EXPECTED BENEFITS:***

- o Reduced systemic toxicity for improved safety profile
- o Concomitant Therapy (complements systemic therapies)
- o Increased utility in a wider range of patients

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HE Filter Expected to Significantly Enhance Procedure and Market Opportunity

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# Product Development Pipeline

	Initial Opportunity	Near Term (< 5 years)	Intermediate Term (> 5 years)
EU	<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> <li>Leverage strong data in melanoma and NET liver mets</li> </ul>	<ul style="list-style-type: none"> <li>HCC and CRC livers met global clinical trials</li> <li>Apparatus improvements</li> </ul>	<ul style="list-style-type: none"> <li>Additional drugs</li> <li>Other organs</li> </ul>
US	<ul style="list-style-type: none"> <li>Melanoma liver mets</li> <li>Proprietary drug-melphalan &amp; apparatus</li> <li>EAP - melphalan</li> </ul>	<ul style="list-style-type: none"> <li>HCC and CRC liver mets global clinical trials - melphalan</li> <li>Apparatus improvements</li> </ul>	<ul style="list-style-type: none"> <li>Additional drugs</li> <li>Other organs</li> </ul>
ASIA	<ul style="list-style-type: none"> <li>Leverage CE Mark approval</li> <li>Leverage strong data in melanoma and NET liver mets</li> <li>3<sup>rd</sup> party melphalan</li> </ul>	<ul style="list-style-type: none"> <li>HCC and CRC liver mets global clinical trials - melphalan</li> <li>Drug-melphalan &amp; apparatus</li> </ul>	<ul style="list-style-type: none"> <li>Additional drugs</li> <li>Other organs</li> </ul>

**Robust Development Program Planned**

# Clinical Data Development Plans

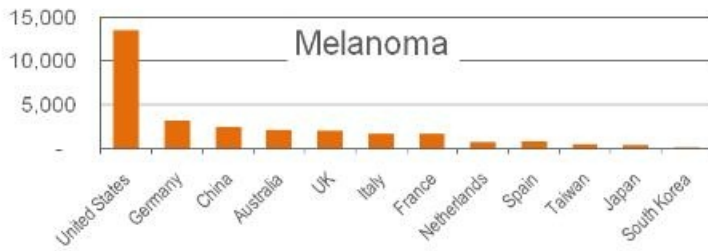
- Utilize High Efficiency (HE) Filter
  - Concomitant therapy to complement standard of care treatments
  - Increase safety (reduce systemic side effects) of procedure
  - Small Pk study commencing in Q4 in Australia
- Enroll clinical trials in 2012 to expand data and enhance commercial adoption
  - Expanded Access Program (EAP) in U.S. for metastatic melanoma at 4-5 centers
  - 2 L HCC: randomized, Global Phase 3 of Chemosaturation vs BSC for sorafenib refractory patients (registration study for expanded labeling of melphalan)
  - 1L HCC: randomized, Global Phase 4 sorafenib vs Chemosaturation in first line setting
  - Metastatic colorectal (mCRC): Phase 2, single arm for patients refractory to 1L therapy
- Future possibilities may include: use in adjuvant setting in melanoma, combination therapy with ipilimumab, combination with SOC in mCRC, combination with resection

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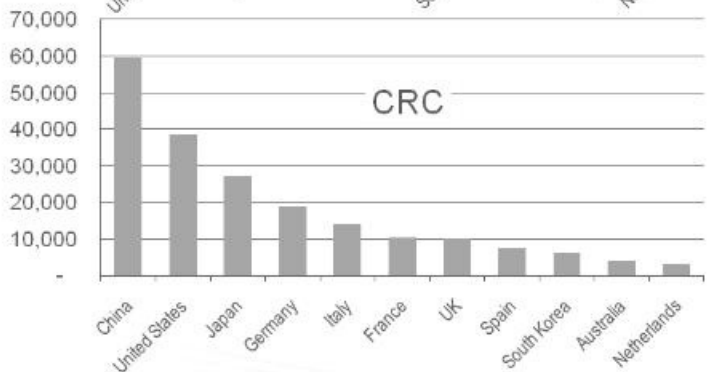
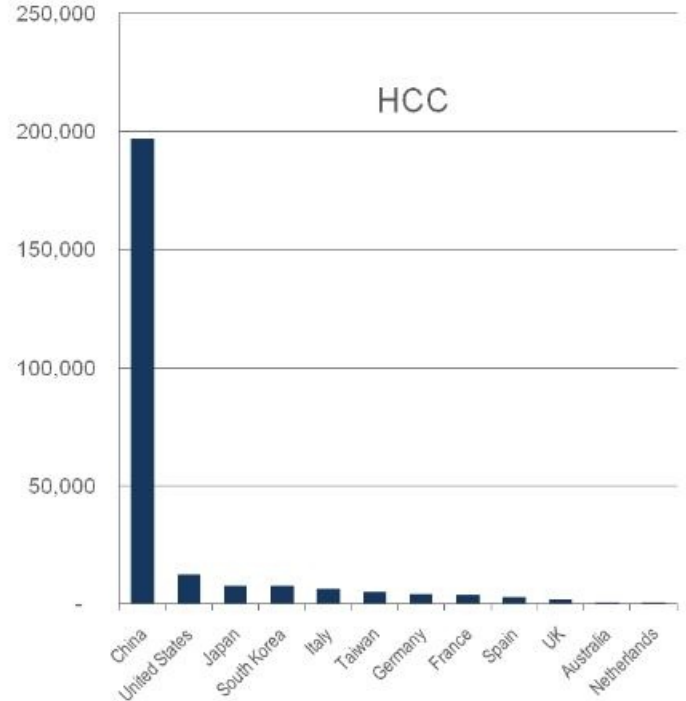
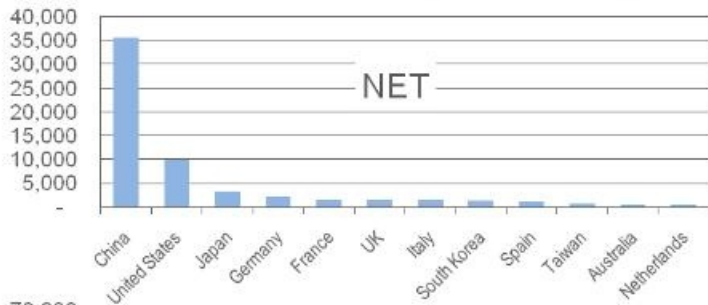
Goal Of Establishing Chemosaturation As Standard of Care For Disease Control In The Liver

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# Market Opportunity\* by Disease (patients)



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



# EEA Landscape

- CE Mark device approval covers 30 countries in the European Economic Area (EEA)
- Indication is for “intra-arterial delivery of chemotherapeutic agent (melphalan hydrochloride) to the liver”
- Hospitals procure melphalan separately from existing sources
- Melphalan for injection approved in 14 countries, but commercially available in remaining EEA countries
- Estimate potentially applicable to ~100,000 patients annually
- 6 top countries (DE, UK, FR, IT, SP, NL) represent ~70% of total patient population

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Large European Market Opportunity Concentrated in Six Countries

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# European Commercialization Plans



**Objective:** broad commercial adoption

**Major Assumptions:**

- HE filter available for full commercial launch ( Q3 2012)
- 6-8 Centers of Excellence for training
- Initiate test market in 2011 for 6 months to validate assumptions and finalize model
- Full commercialization in 2012

**Tactics & Execution:**

- Market to medical oncologists via contract sales organization (CSO) to create “Push”
- Sell to hospital-based interventional radiologists and surgeons with combination of direct sales and distributors to create “Pull”
- Establish European patient education & awareness programs (PR, website)
- Leverage existing new technology reimbursement channels, while pursuing permanent procedure reimbursement via Health Technology Assessment (HTA)
- New clinical trials to generate additional data for HCC & mCRC

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## Strategy and Tactics to Address All Key Constituents

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# European Marketing Considerations

## **Reimbursement:**

- o No centralized EEA device reimbursement body - regional and national systems
- o Devices typically reimbursed under DRG as part of a procedure
- o Immediate reimbursement plans:
  - Utilize existing codes where permitted until permanent reimbursement established (e.g. Italy)
  - Apply for funding under new technology programs (e.g. NUB in Germany and HAS in France)
  - Other oncology therapies currently reimbursed, despite lacking randomized data
- o Retained reimbursement experts to obtain new procedure specific coding and payment
- o Developing Health Technology Assessment (HTA)
- o Focused on highlighting clinical value proposition and demonstrating cost effectiveness

## **Melphalan:**

- o Delcath approved in the EEA for the intra-arterial administration of melphalan to the liver
- o Physicians will continue to procure melphalan independently
- o Clinical experience in EEA and publications support use of melphalan for disease control in the liver

## **Clinical Data:**

- o Delcath Phase 3 and Phase 2 data supplements extensive surgical IHP data with melphalan
- o Expect to initiate additional studies with Standard of Care (SOC) in 2012 with availability of HE filter in HCC, and metastatic CRC
- o Marketing to medical oncologists will be data driven

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Required Elements In Place To Support Commercial Launch

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# European Interim New Technology Reimbursement Programs



Interim New Technology Payment Programs Already Exist in Major European Markets

# Market by Disease - EEA Device Only

	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**

# U.S. FDA Regulatory Status

- On February 22, 2011, received Refusal to File (RTF) letter from the FDA
  - § Manufacturing plant inspection timing
  - § Product and sterilization validation
  - § Additional statistical analysis clarification
  - § Additional safety data
- RTF stated that safety information provided was insufficient to allow FDA to accept our application and review the overall risk/benefit profile
- FDA & SPA approved CRF's did not collect all hospitalization data in the patient records in an effective manner
- Follow-up meeting with FDA held in April 2011 to review proposed plan of action which includes:
  - Collection of all available safety information in new CRF for all 186 patients in the Phase I, II and III clinical trials
- No additional studies or generation of new data requested

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Intend to Submit Revised NDA By End of 2011

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# Market by Disease\* - USA

Liver Metastasis	Potential Market # Patients	Potential Market # Procedures (Avg 2.5/patient)	Potential Market (\$MM) \$20K ASP **
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

# U.S. Commercialization Strategy

- Initial focus on leading cancer centers and referring community hospitals
- Market to Medical Oncologists via CSO
- Direct Strategy to sell to Interventional Radiologists and Surgeons: 12 Sales & Medical Science Liaison territories ultimately expanding to as many as 60 territories as revenues ramp
- 5 Clinical Specialists initially to support site initiation and training
- Utilize top centers from Phase III trial as Centers of Excellence for training and support

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Direct Sales Model Supplemented With CSO Detailing Program

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# U.S. Reimbursement Strategy

**Strategy:** intend to seek chemosaturation specific codes based upon value proposition relative to other cancer therapies

- o Physician:
  - Applied for CPT Category III code
  - Convert the Category III code to Category I following FDA approval
- o Hospital:
  - Apply for new ICD-9/10 procedure code to capture full procedure of hepatic isolation and chemosaturation
  - Request new DRG based on costs above those of existing DRGs and clinical dissimilarity to other hepatic procedures in current DRGs

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Pursuing New Specific Codes For Chemosaturation Procedure

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# Strategy For Asia, Ex US America's, MEA and Australia

- Intend to leverage CE Mark to obtain reciprocal regulatory approvals for our Delcath Hepatic CHEMOSAT System
- Utilize existing 3<sup>rd</sup> party melphalan available to physicians
- Seek to secure strategic partners and specialty distributors
- Intend to initiate melphalan HCC trial in Taiwan with partner Chi-Fu in 2012

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Combination of Direct Sales, Strategic Partnerships & Specialty Distributors

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# Market by Disease - Australia/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 1,2,3,4
<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
4. Assumes sales by distributors

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



# Intellectual Property

## Patent Protection

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

## Trade Secret Protection

- Developed High Efficiency (HE) filter media via new manufacturing processes

## 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
  - Provides 7 years of marketing exclusivity post FDA approval
- Additional Orphan Drug applications to be filed for other drugs and indications, including melphalan for HCC and CRC

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Multiple Levels of Protection

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# Deep and Experienced Management Team

Executive	Title	Prior Affiliation(s)	Years of Experience
Eamonn Hobbs	President and CEO	AngioDynamics, E-Z-EM	30
David McDonald	CFO	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, E-Z-EM	29
Peter Graham, J.D.	EVP & General Counsel	Bracco, E-Z-EM	16
John Purpura	EVP, Regulatory Affairs & Quality Assurance	E-Z-EM, Sanofi-Aventis	27
Bill Appling	SVP Operations & Medical Device R&D	AngioDynamics	25
Harold Mapes	EVP, Global Operations	AngioDynamics, Mallinckrodt	25
Dan Johnston, Ph.D.	VP, Pharma R&D	Pfizer, Wyeth	10

**Significant Combination Product Approval and Commercialization Experience**

# FINANCIALS



# Financial Summary

## Financial & Operating Overview

- Follow On Offerings: Raised ~ \$94 million since November 2009
- Burn Rate: Anticipate ~\$3.0 million per month
- Cash: ~ \$53 million at July 31, 2011
- Debt: None
- Shares Out: 48.0 million (54.8 million fully diluted\*)
- Institutional Ownership: ~ 28% at March 31, 2011
- Market Capitalization: ~ \$214 million as of July 31, 2011
- Avg. Daily Volume (3 months) ~ 815,000

As of July 31<sup>st</sup>, 2011 fully diluted includes an additional 4.1 million options at \$5.04, 2.5 million warrants at \$3.51, and 174,682 unvested restricted shares.

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**Balance Sheet Strengthened Significantly in Past Two Years To Support Growth Activities**

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# Company Highlights

- Making established chemotherapeutic drugs work better in target organs
- Initial focus is high dose chemotherapy for improved disease control in the liver
- Successful and highly statistically significant Phase III trial results reported
- Received CE Mark approval for Class III medical device on April 13, 2011
- Positioned to address potential \$3.0 billion European labeled market opportunity
- Objective is to re-file 505(b)(2) NDA to FDA for orphan drug and delivery apparatus by end of 2011
- Potential \$675 million US labeled market opportunity
- Issued patents and orphan drug designations create competitive barriers
- Deep and experienced management team

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Concentrating the Power of Chemotherapy to Improve Disease Control in the Liver

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# 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.

Blake, Simon P., Karen Weisinger, Michael B. Atkins, and Vassilios Raptopoulos. "Liver Metastases from Melanoma: Detection with Multiphasic Contrast Enhanced CT." *Radiology* 213 (1999): 92-96. Print

Ferlay J, Shin HR, Bray F, Forman D, Mathers C and Parkin DM.  
GLOBOCAN 2008, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 [Internet].  
Lyon, France: International Agency for Research on Cancer; 2010. Available from: <http://globocan.iarc.fr>

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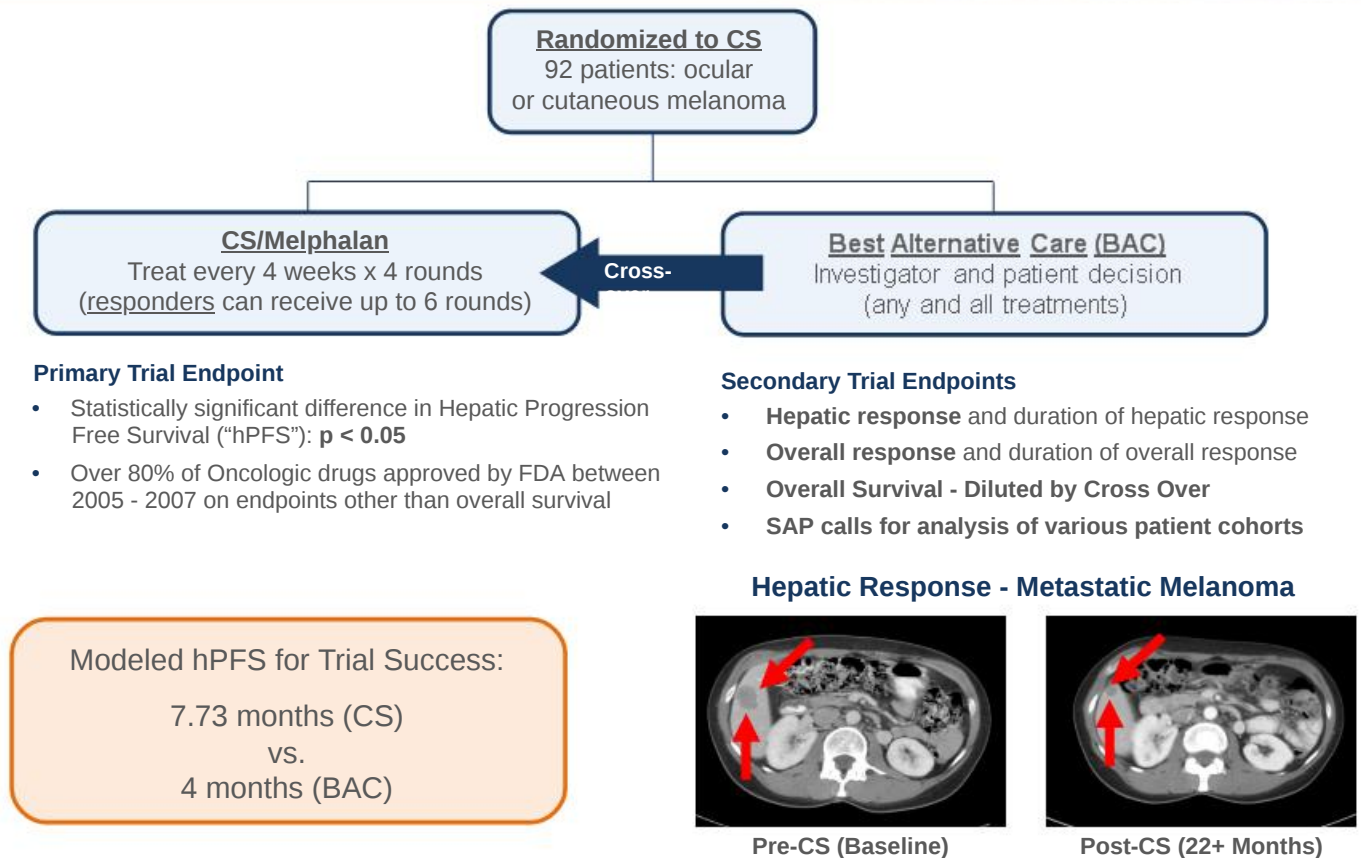
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## Appendix II. - Phase 3 Pivotal Trial Details

# Phase III Clinical Trial Design



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



# ASCO 2010 Presentation of Phase 3 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)

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Strong Clinical Trial Results

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## ASCO 2010 Presentation of Phase 3 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
  - o Treatment related Deaths: 3/40 patients (7.5%) 3/116 procedures (2.6%)
  - o Neutropenic Sepsis (n=2) 5%, Hepatic Failure (n=1) 2.5% (95% tumor burden)
  - o Current approved labeling for Melphalan - 3% to 10% mortality rate.

1. Source: Unger et. al. *Cancer* 2001;91: 1148

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Encouraging Survival Data With Expected Safety Profile

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# Concentrating the Power of Chemotherapy™