

**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): February 14, 2012**

**DEL CATH 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, 35<sup>th</sup> Floor, 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 presented at the 14<sup>th</sup> Annual CEO & Investor Conference on Tuesday, February 14, 2012 and will continue to use 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.

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

**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: February 14, 2012

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



# Investor Presentation

(NASDAQ: DCTH)

February 2012

# 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, but not limited to; uncertainties relating to the time required to build inventory and establish commercial operations in Europe, CE Marking for the Generation Two CHEMOSAT system, adoption, use and resulting sales, if any, for the CHEMOSAT system in the EEA, our ability to successfully commercialize the CHEMOSAT 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 results of 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 our filings with the Securities and Exchange Commission including the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K and our Reports on Form 10-Q and Form 8-K.*

## Delcath Systems – Company Highlights

- A specialty pharmaceutical and medical device company focused on oncology
- Initial focus on delivering high dose chemotherapy to improve disease control of cancers in the liver
- CHEMOSAT CE Mark approved – indication permits broad use in liver cancers. Commenced initial treatment procedures in Europe
- Addressing potential multi-billion dollar European market opportunity
- Unique device/drug product with statistically significant clinical trial results
- Seeking regulatory approval in multiple international markets
- Intend to file US NDA in 2Q2012 seeking initial indication for metastatic melanoma to the liver
- IP and orphan drug designations create competitive barriers

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Concentrating the Power of Chemotherapy for Disease Control in the Liver

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- CHEMOSAT is a drug delivery system designed for regional chemotherapy for cancers in the liver
  1. Utilize three catheters to **ISOLATE** the circulatory system of the liver
  2. **SATURATE** the liver with a high dose of anti-cancer agent (melphalan) to destroy the tumors (both visible and invisible)
  3. **FILTRATE** the chemo-drug laden blood through Delcath's proprietary filtration system prior to returning it to the patient

- ✓ Control systemic exposure and related side effects
- ✓ The procedure is minimally invasive and repeatable

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Concentrating the Power of Chemotherapy for Disease Control in the Liver

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## Initial Focus on Cancers of the Liver

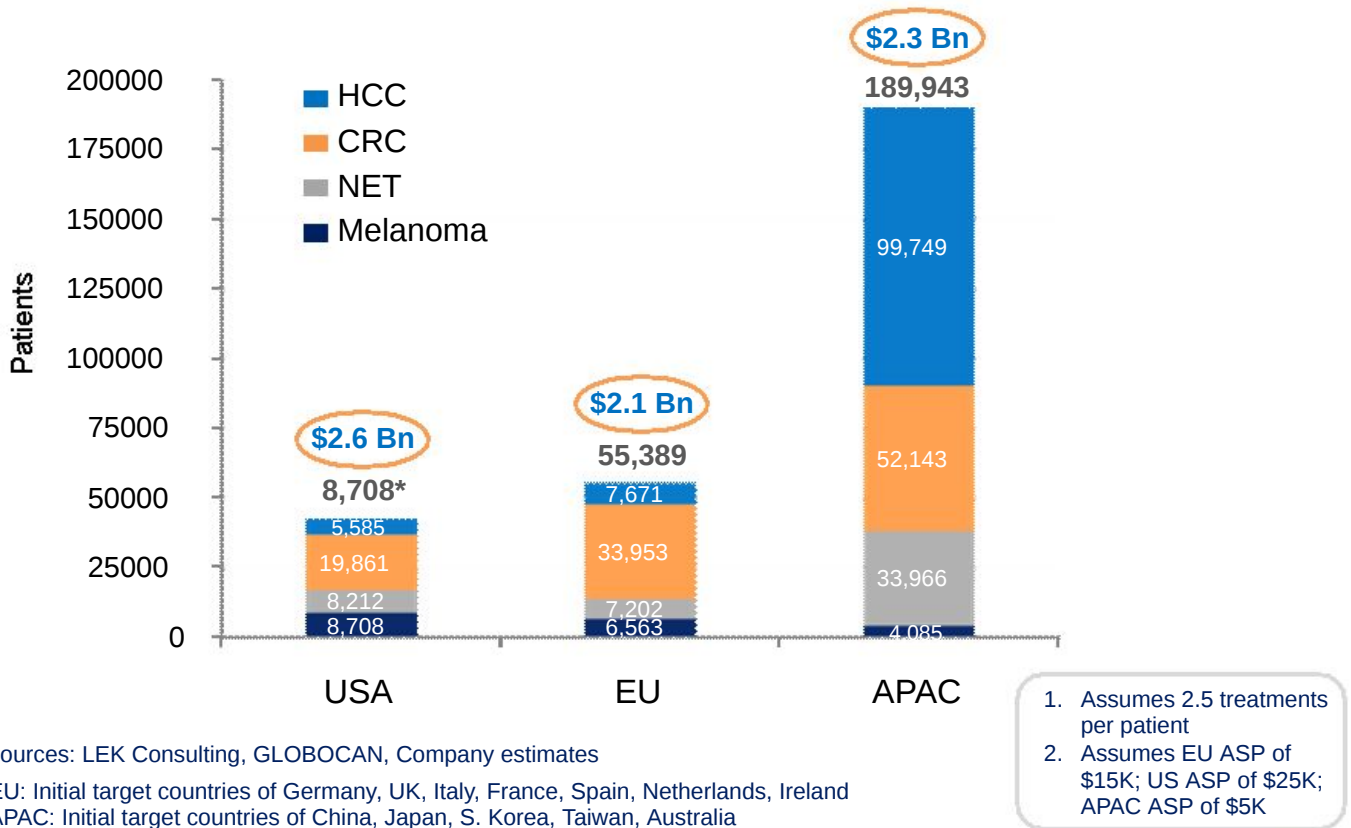
- Few effective therapies are available for cancers of the liver
  - ❑ Large patient population diagnosed annually with primary or metastatic liver cancer
  - ❑ The liver is often the life limiting organ for cancer patients and one of the leading causes of cancer death
  - ❑ Prognosis after liver involvement is poor
- Multi-billion dollar annual global revenue market opportunity
- CHEMOSAT is uniquely positioned to treat the entire liver as standalone or complementary therapy

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Major Global Unmet Medical Need and Significant Market Opportunity

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# CHEMOSAT Addresses Potential Multi-Billion Dollar Market



**Estimated \$7 Billion Annual Global Revenue Opportunity, Near Term Primarily in Europe**

# CHEMOSAT European Commercialization

- CE Mark covers 30 countries in Europe
- Focus on top 6 countries (DE, UK, FR, IT, SP, NL) and Ireland
- Broad indication is for “percutaneous intra-arterial delivery of a chemotherapeutic agent (melphalan hydrochloride) to the liver”
- Melphalan for injection approved in 14 countries and commercially available
- Hospitals procure melphalan separately from existing sources
- EU headquarters in Galway, Ireland
- Direct and indirect selling channels
- Push and pull marketing strategy

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Large European Market Opportunity Concentrated in Target Countries

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## CHEMOSAT Training and Marketing Commenced in Europe

- Entered training and marketing agreements with leading cancer centers in Europe
  - Institute of European Oncology (IEO), Milan, Italy
  - Johann Wolfgang Goethe (JWG) University Hospital, Frankfurt, Germany
- Training completed and first patients treated at IEO
  - Ocular melanoma and Gastric cancer liver mets
- Expect training and patient treatments in JWG University Hospital, Frankfurt, Germany in February
- Agreements with additional leading cancer centers expected in France, UK, Spain, the Netherlands, and Ireland in 1H2012

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Continue Training And Marketing Centers Roll-Out

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Team at Institute of European Oncology Performs 1<sup>st</sup> EU CHEMOSAT Procedure

January 31, 2012

# Existing Liver Cancer Treatments Have Limitations

Treatment	Advantages	Disadvantages
<b>Systemic</b>	<ul style="list-style-type: none"><li>– Non-invasive</li><li>– Repeatable</li></ul>	<ul style="list-style-type: none"><li>– Systemic toxicities</li><li>– Limited efficacy in liver</li></ul>
<b>Regional</b> (e.g., IHP)	<ul style="list-style-type: none"><li>– Therapeutic effect</li><li>– Targeted</li></ul>	<ul style="list-style-type: none"><li>– Invasive/limited repeatability</li><li>– Multiple treatments are required, not possible</li></ul>
<b>Focal</b> (e.g. surgery, radioembolization or SIRT, chemoembolization or TACE, radio frequency ablation or RFA)	<ul style="list-style-type: none"><li>– Partial removal or treatment of tumors</li></ul>	<ul style="list-style-type: none"><li>– 80-90% unresectable</li><li>– Invasive and/or limited repeatability</li><li>– Treatment is limited by tumor size, number of lesions and location</li><li>– “See a tumor, treat a tumor”</li></ul>

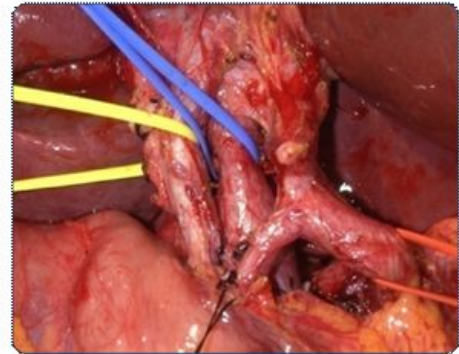
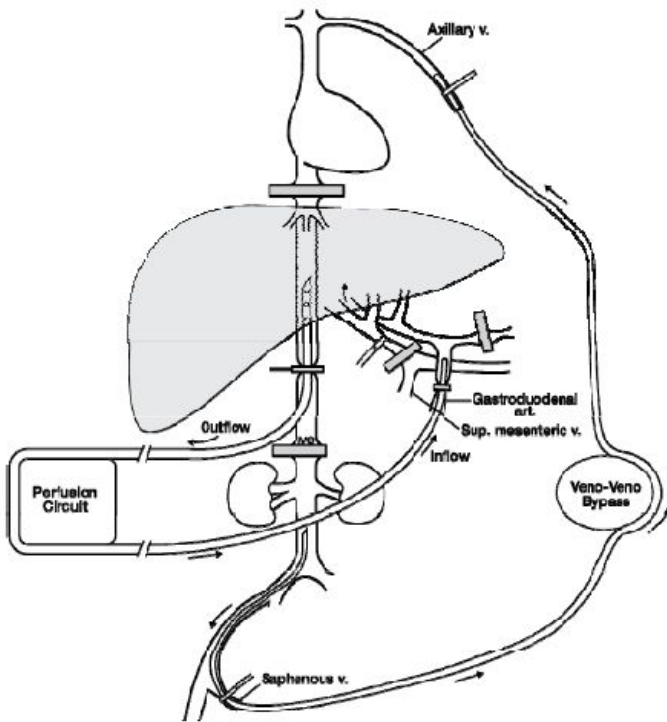
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Unmet Medical Need Exists for More Effective Liver Cancer Treatments

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# CHEMOSAT System – Where It All Began

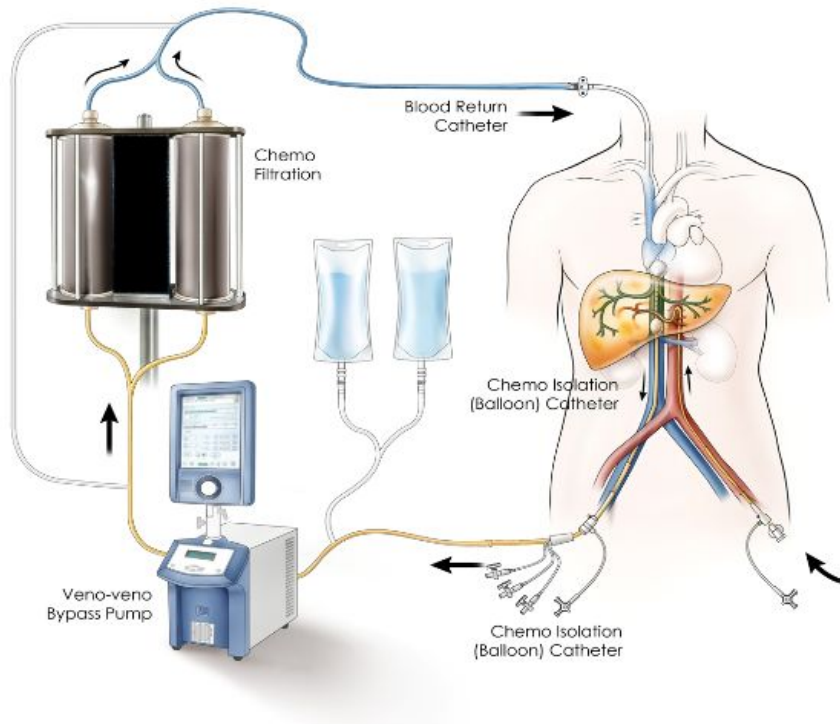
## Open Surgical IHP



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



# The Delcath CHEMOSAT System



## Three Steps

- 1) ISOLATION
- 2) SATURATION
- 3) FILTRATION

## Advantages

- No more open surgery
- Minimally invasive, repeatable
- Treats entire liver (macro and micro)
- Allows for over 100x effective dose escalation of drug agents at tumor site
- Improved disease control in the liver
- Minimizes systemic toxicities
- Complements systemic therapy

Note: Image not to scale.

Minimally Invasive, Repeatable Liver Procedure That Could Complement Systemic Therapy

# 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 little to no hepatic toxicity
- Manageable systemic toxicities associated with Neutropenia and Thrombocytopenia
- Drug dosing **12x higher** than FDA-approved dose via systemic IV chemotherapy
- Dose delivered to tumor is over **100x higher** than that of systemic IV chemotherapy

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An Established Drug For Liver Cancer Therapy

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# What CHEMOSAT Offers

## Patients:

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

## Physicians:

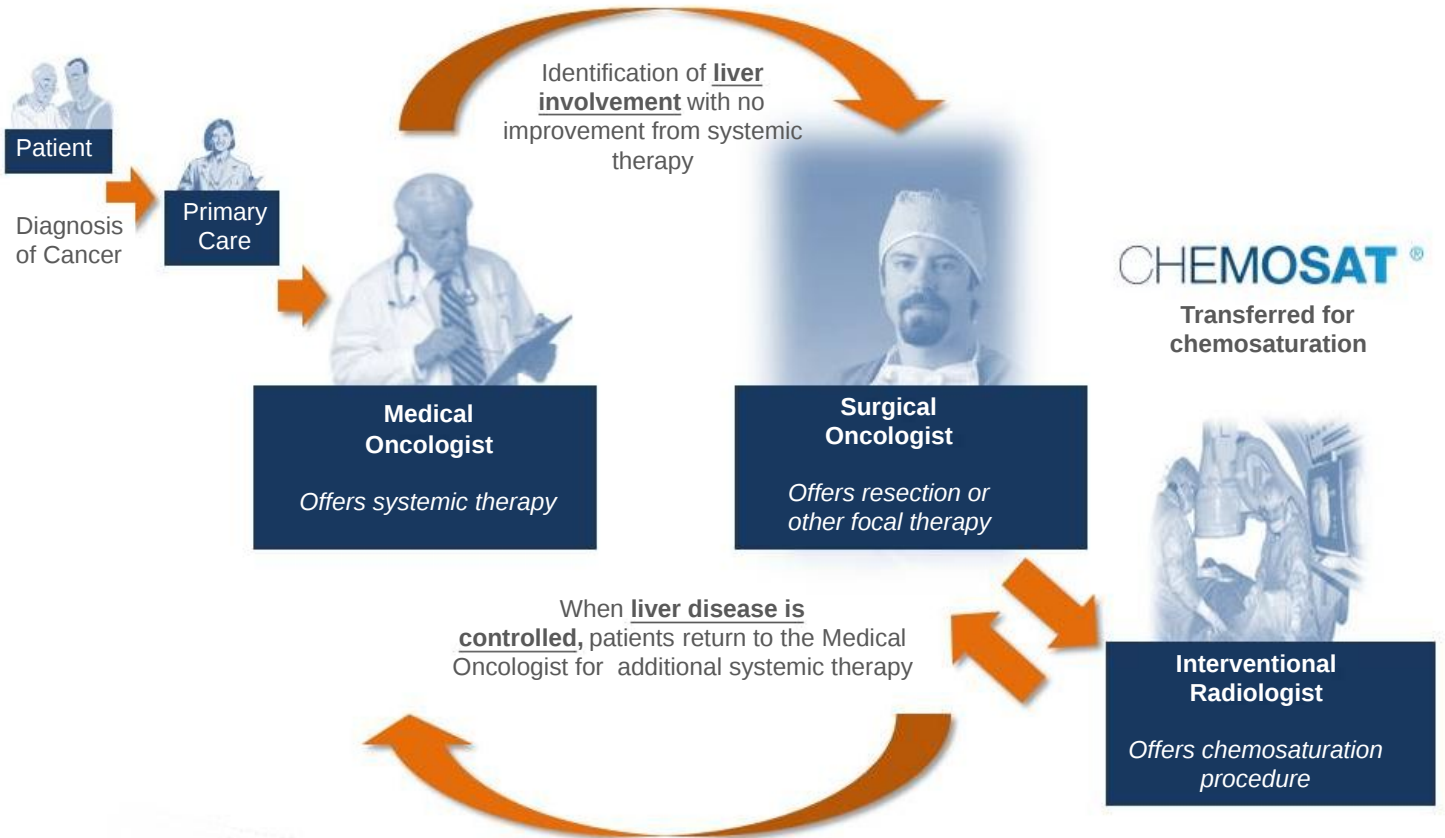
- o Novel, targeted liver cancer treatment to complement other cancer therapies
- o Repeatable, percutaneous procedure
- o Ability to treat the entire liver, including both visible and micro tumors
- o Ability to continue treating patients for extra-hepatic disease

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Compelling Clinical Outcomes and Value Proposition

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# Current Patient Referral Path



# Positive Phase III Results\*

- **Primary endpoint exceeded, p value = 0.0001, hazard ratio of .35**
  - Treatment arm shows 5x median hepatic progression free (hPFS) survival compared to control arm
  - CS/PHP median hPFS of 8.0 months compared to 1.6 months 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 (9.8 months compared to 9.9 months)
  - CS/PHP median overall PFS of 6.7 months vs 1.6 months for BAC
- **OS exploratory cohort analysis favorable**
  - Median survival of 9.8 months for treatment arm compared to 4.1 months non-crossover BAC patients
  - Median survival of 11.4 months for all patients treated with melphalan, including crossover
  - 9 CS/PHP-treated patients and 3 BAC-treated patients still alive as of 12/2011
- **Safety profile – expected and consistent with currently approved labeling for melphalan**
  - 30-day deaths on PHP: 3/44 patients (6.8%)
    - 1 Neutropenic Sepsis (2.3%); 1 Hepatic Failure 2.5% (95% tumor burden); 1 gastric perforation
  - 30-day deaths on BAC: 3/49 patients (6.1%)

\* Updated Investigator results presented at 2011 ECCO/ESMO Annual Meeting

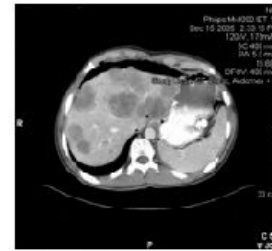
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**Trial Outcomes Favorable and Consistent with Special Protocol Assessment**

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# Phase 2 NCI Trial – Metastatic Neuroendocrine (mNET) Cohort

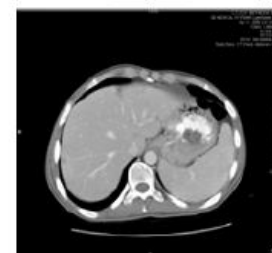
Phase 2 mNET Tumor Cohort (n=24)*	
	Number (n)
<b>Primary Tumor Histology</b>	
Carcinoid	4
Pancreatic Islet Cell	20
<b>Response</b>	
Not Evaluable (Toxicity, Incomplete Treatment, Orthotopic Liver Transplantation)	4
Progressive Disease	2
Minor Response / Stable Disease	4
<b>Partial Response (30.0% - 99.0% Tumor Reduction)</b>	<b>13</b>
<b>Complete Response (No Evidence of Disease)</b>	<b><u>1</u></b>
<b>Objective Tumor Response</b>	<b>14</b>
<b>Objective Tumor Response Rate</b>	<b>70%</b>
<b>Duration (months)</b>	
Median Hepatic PFS	15.5
Overall Survival After CS	30.4



Pre-CS  
(Baseline)



Post-CS #1  
(+6 Weeks)



Post-CS #2  
(+4 Months)

\*Presentation at ECCO/ESMO 2011 annual meeting

Compelling Clinical Data in Attractive mNET Market

## Phase 2 NCI Trial – HCC Cohort

- Hepatocellular carcinoma (HCC) is the most common primary cancer of the liver, with approximately 749,000\* new cases diagnosed worldwide annually
- Nine patients with tumors of hepatobiliary origin: five HCC patients and four cholangiocarcinoma patients
- Both groups received CHEMOSAT procedures and had positive efficacy signals
- The responses were especially encouraging in the HCC group and consisted of confirmed partial response or durable stable disease
- Safety profile – expected and consistent with pivotal FDA Phase 3 melanoma trial
- Plan to initiate HCC trials with CHEMOSAT in 2H2012

\*Source: GLOBOCAN

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Encouraging Initial Positive Signal For Primary Liver Cancer

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# Melphalan Efficacy for Metastatic Colorectal Cancer

- Substantial clinical evidence of benefit of using melphalan to treat mCRC via isolated hepatic perfusion (IHP) procedure
  - ❑ Over 800 patients treated in 15 studies since 1998
  - ❑ Patients treated only once
  - ❑ Median response rate of 47% (range 29%-76%)<sup>1</sup>
- Delcath Phase 2 NCI CHEMOSAT Trial – mCRC Cohort
  - ❑ Challenges enrolling at NCI
  - ❑ 16 patients treated since 2004
  - ❑ Inconclusive efficacy due to advanced disease status (generally 5<sup>th</sup> or 6<sup>th</sup> line)
  - ❑ Safety profile – expected and consistent with pivotal FDA Phase 3 melanoma trial
- Plan to initiate mCRC trial with CHEMOSAT melphalan in 2H2012

1. van Iersel LB, Koopman M, Van D, V, et al. *Ann Oncol.* 2010;21:1662-7.

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Strong Rationale For Using CHEMOSAT With Melphalan To Treat mCRC

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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 medical device</li> <li>3<sup>rd</sup> party melphalan</li> <li>Gen 2 melphalan CE Mark</li> </ul>	<ul style="list-style-type: none"> <li>Doxorubicin system CE Mark</li> <li>mCRC and HCC clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>CHEMOSAT for additional drugs</li> <li>CHEMOSAT for other organs (lung and brain)</li> </ul>
ASIA	<ul style="list-style-type: none"> <li>CHEMOSAT (Melphalan) in Australia and Hong Kong</li> <li>3<sup>rd</sup> party melphalan</li> </ul>	<ul style="list-style-type: none"> <li>CHEMOSAT (Melphalan) in S. Korea, Japan</li> <li>CHEMOSAT (Doxorubicin) in China and Taiwan</li> <li>3<sup>rd</sup> party doxorubicin</li> </ul>	<ul style="list-style-type: none"> <li>CHEMOSAT for additional drugs</li> <li>CHEMOSAT for other organs (lung and brain)</li> </ul>
US	<ul style="list-style-type: none"> <li>Melanoma liver mets</li> <li>Proprietary drug-melphalan &amp; CHEMOSAT</li> </ul>	<ul style="list-style-type: none"> <li>mCRC and HCC indications</li> </ul>	<ul style="list-style-type: none"> <li>CHEMOSAT for additional drugs</li> <li>CHEMOSAT for other organs (lung and brain)</li> </ul>

Development Aligned to Address Significant Market Opportunity

# CHEMOSAT Doxorubicin Development

- Multiple published phase I/II studies from MD Anderson Cancer Center and Yale with percutaneous hepatic perfusion (PHP) and Kobe University using doxorubicin show promising response rates for HCC\*
- **STATUS:**
  - First pass removal efficiency 95% in initial in vitro studies
  - Utilize new trade secret manufacturing process
  - Intend to file and seek CE Mark approval in 2H2012
  - Plan to use CHEMOSAT doxorubicin in Asia Phase III 2L HCC trials
- **EXPECTED BENEFITS**
  - Multiple treatments
  - Reduced systemic toxicity for improved safety profile
  - Concomitant Therapy (complements systemic therapies)

\* See Appendix for list of studies

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Addressing the Large HCC Market Opportunity in China

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# Clinical Development Program

- **Goal**

- Expand indications for HCC and mCRC with US registration trials
- Generate robust clinical data to support commercialization

- **Potential 2012 clinical trials**

- HCC: Global Phase 2 randomized 1L CHEMOSAT Melphalan vs. Sorafenib
- HCC: US registration – Global Phase 3 randomized 2L CHEMOSAT Melphalan vs. Best Supportive Care (BSC) for Sorafenib failure
- HCC: Asia Phase 3 randomized 2L CHEMOSAT Doxorubicin vs. Best Supportive Care (BSC) for Sorafenib failure
- mCRC: Global Phase 2 signal seeking/safety 2L CHEMOSAT Melphalan
- mCRC: US registration – Global Phase 3 randomized 2L CHEMOSAT Melphalan vs. Approved Alternatives

- US Expanded Access Program (EAP) for metastatic Melanoma

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Establish CHEMOSAT As The Standard Of Care (SOC) For Disease Control In The Liver

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# Generation Two CHEMOSAT Melphalan

## STATUS:

- Consistent first pass removal efficiency of 98% or better in both *in vitro* and pre-clinical GLP animal studies
- New trade secret manufacturing process for filter medium
- Filed for CE marking for Gen Two
- Anticipate approval in 1Q2012

## EXPECTED BENEFITS:

- Reduced systemic toxicity
- Concomitant Therapy (complements systemic therapies)
- Increased utility in a wider range of patients

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Gen Two Filter Has The Potential to Enhance Procedure and Market Opportunity

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# European Commercialization Strategy



## Strategy:

- Focus efforts in Target Countries
- 8-10 leading EU cancer centers as initial training centers
- Push and Pull marketing and selling strategy
- Validate business model and demonstrate scalability

## Tactics & Execution:

- Educate medical oncologists via contract organization – Medical Science Liaison (MSL)
- Sell to hospital-based interventional radiologists, surgeons and C-suite decision makers with combination of direct sales and distributors
- Establish European patient education & awareness programs (PR, website)
- Leverage existing new technology reimbursement channels, while pursuing permanent procedure reimbursement via Health Technology Assessment (HTA)
- Clinical trials to generate additional data for CRC and HCC to support revenue ramp up

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Currently At Initial Launch Phase

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# European Reimbursement Considerations

- No centralized pan-European medical device reimbursement body – regional and national systems
- Devices typically reimbursed under Diagnosis Related Groups (DRG) as part of a procedure
- Immediate reimbursement plans:
  - Utilize existing codes where permitted until permanent reimbursement established (e.g. Italy)
  - Apply for funding under existing New Technology Payment programs (e.g. NUB in Germany and HAS in France)
  - Other oncology therapies currently reimbursed, despite lacking randomized data

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Reimbursement Mechanisms In Place To Support Commercial Launch

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# European Interim New Technology Reimbursement Programs



NUB (temporary reimbursement) application in place  
Hospitals need to apply directly  
2010 , out of 13865 requests 7480 representing 74 technologies were given temporary reimbursement status



Extra Tariff Funding negotiated at regional level  
Italy is one of the most active countries seeking fast track funding schemes for innovative technology



Extra funding made available for innovative technologies  
Premiums to be negotiated with the technology assessment agency for temporary reimbursement



Pass through payments negotiated directly with individual trusts  
This funding can be applied for up to 2 years



Possibility of agreements individual hospitals.  
Financing of healthcare budgets set at regional level with differences on reimbursement levels  
Implementation of shared risk agreements

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Interim New Technology Payment Programs Already Exist in Major European Markets

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# U.S. FDA Regulatory Status

- Pre-NDA submission meeting with FDA conducted in January 2012
  - Satisfied with FDA response
  - Addressed RTF related issues
    - Manufacturing plant inspection timing
    - Product and sterilization validation
    - Additional statistical analysis clarification
    - Additional safety data
- Continued progress in finalizing data entry and monitoring
  - Completed data migration to new FDA compliant database
  - Created new Case Report Form (CRF)
- Plan to file NDA submission in Q2 2012

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Progress On Track to Submit NDA

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# U.S. Commercialization Strategy

- Initial focus on leading cancer centers and referring community hospitals
- Educate Medical Oncologists via Contract Medical Science Liaison (MSL)
- Direct Strategy to sell to Interventional Radiologists and Surgeons: 12 Sales 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 Channels Supplemented With Contract MSLs

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## U.S. Reimbursement Strategy

- Intend to seek chemosaturation specific codes based upon value proposition relative to other cancer therapies
  - ❑ Physician:
    - Use existing miscellaneous DRG procedure code
    - Apply for a CAT I code following FDA approval
  - ❑ 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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# International Strategy beyond EU and US

- Leverage CE Mark to obtain reciprocal regulatory approvals for CHEMOSAT System in other international markets
- International regulatory submissions status:
  - Application submitted, potential approval
    - Australia - 2012
    - Hong Kong - 2012
    - S. Korea - 2013
    - Singapore - 2013
  - Intend to submit applications
    - Israel
    - Canada
    - Mexico/Argentina/Brazil
    - Russia
    - India
    - Japan
    - China and Taiwan
- Utilize 3<sup>rd</sup> party melphalan and doxorubixin available to physicians

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Combination of Strategic Partnerships and Specialty Distributors

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# 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 improved 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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# Experienced Management Team

Executive	Title	Prior Affiliation(s)	Years of Experience
Eamonn Hobbs	President and CEO	AngioDynamics, E-Z-EM	31
Graham Miao, Ph.D	EVP & CFO	D&B, Pagoda Pharma, Schering-Plough, Pharmacia, JP Morgan	22
Krishna Kandarpa, M.D., Ph.D.	CMO and EVP, R&D	Harvard, MIT(HST), Cornell, UMass	32
Agustin Gago	EVP, Global Sales & Marketing	AngioDynamics, E-Z-EM	30
Peter Graham, J.D.	EVP, General Counsel & Global Human Resources	Bracco, E-Z-EM	17
David McDonald	EVP Business Development	AngioDynamics, RBC Capital Markets	29
John Purpura	EVP, Regulatory Affairs & Quality Assurance	E-Z-EM, Sanofi-Aventis	28
Harold Mapes	EVP, Global Operations	AngioDynamics, Mallinkrodt	26
Bill Appling	SVP Medical Device R&D	AngioDynamics	26
J. Chris Houchins	SVP, Clinical and Medical Affairs	Arno, Schering-Plough, Pfizer, Pharmacia, GD Searle	21
Dan Johnston, Ph.D.	VP, Pharmaceutical R&D	Pfizer, Wyeth	11

# FINANCIALS



## Financial Update

- Follow-On Offerings: Raised ~ \$94 million since November 2009
- Financing Program: \$39.75 million At-The-Market (ATM) equity offering program since December 29, 2011
- Cash: \$30.8 million at December 31, 2011 (unaudited)
- Burn Rate: \$40.1 million full year 2011 (unaudited)
- Debt: None
- Shares Outstanding: 48 million (~55 million fully diluted\*)
- Institutional Ownership: 22% at December 31, 2011
- Market Capitalization: \$ 204 million as of February 9, 2012
- Avg. Daily Volume (3mo) 675,000

As of December 31, 2011 fully diluted includes an additional 4.1 million options at \$5.09, 2.5 million warrants at \$3.51, and 193,532 unvested restricted shares.

## 2012 Milestones

- First patients treated with CHEMOSAT melphalan in Europe – 1Q
- Execute contract for MSL services in EU – 1Q
- Secure agreements with 6-8 leading cancer centers in EU – 1H
- Obtain CE Mark for Gen 2 CHEMOSAT melphalan – 1Q
- US NDA submission in 2Q 2012 and acceptance in 3Q 2012
- Submission for publications of Phase 3 data and mNET arm of Phase 2 data – 2H
- First patients enrolled in mCRC and HCC CHEMOSAT melphalan studies, EAP – 2H
- Submit and seek approval of CE Mark for CHEMOSAT doxorubicin – 2H
- Potential Asia strategic partnership –dedicated BD with China a top priority





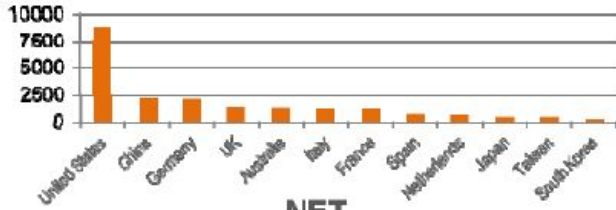
# Appendices



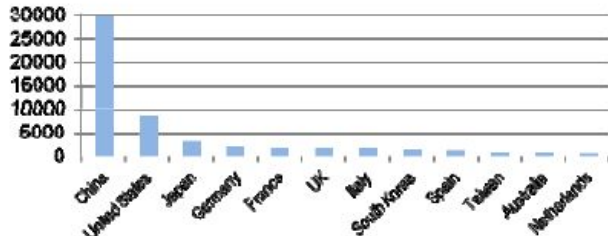
**Appendix I**  
**CHEMOSAT Market Opportunity  
by Disease and Target Counties**

# Market Opportunity by Disease (patients)

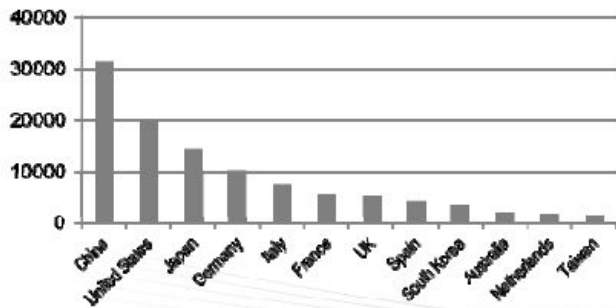
Melanoma



NET



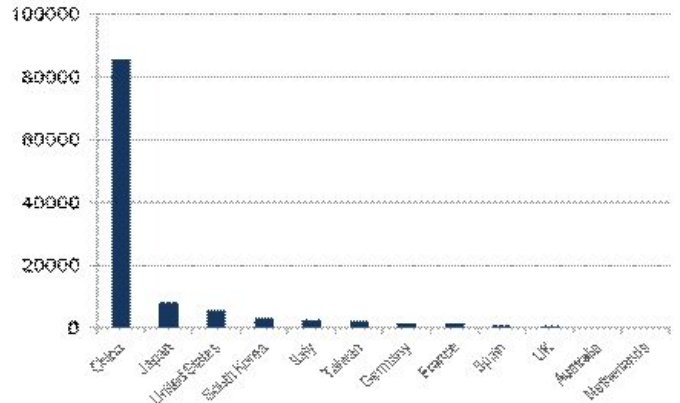
CRC



38 DELCATH SYSTEMS, INC

- Europe – Largest near-term opportunity
- CRC – Largest opportunity worldwide
- Melanoma – Largest opportunity is in US
- China- Largest opportunity for HCC

HCC



## Market Opportunity defined as Total Potential Market (TPM) for CHEMOSAT®

1. Primary cancer incidence
2. Adjusted for predominant disease in the liver (primary or metastatic cancer)
3. Adjusted for addressable patients via Delcath CHEMOSAT®

Sources: LEK Consulting, GLOBOCAN, Company estimates

# Europe Market by Disease – Device Only

	Germany (Direct)	UK (Direct)	France (Indirect)	Italy (Indirect)	Spain (Indirect)	Netherlands (Direct)	Ireland (Direct)	Total Potential (patients)	Potential Market (\$ MM) <sup>1,2,3</sup>
<b>Total Potential Market #Patients</b>									
Ocular Melanoma	404	297	295	285	197	79	19	1,576	\$ 62
Cutaneous Melanoma	1,625	994	753	801	360	379	73	4,987	\$ 206
CRC	9,902	5,300	5,475	7,281	4,016	1,644	335	33,953	\$1,339
HCC (Primary)	1,637	720	1,514	2,597	1,087	82	35	7,671	\$277
NET	1,783	1,336	1,353	1,299	974	360	98	7,202	\$ 281
<b>TOTAL</b>	<b>15,351</b>	<b>8,647</b>	<b>9,389</b>	<b>12,263</b>	<b>6,634</b>	<b>2,545</b>	<b>560</b>	<b>55,389</b>	<b>\$ 2,166</b>

Sources: LEK Consulting, GLOBOCAN, Company estimates

1. Assumes 2.5 treatments per patient
2. Assumes ASP of ~\$15K USD
3. Assumes mix of direct sales and distributors

**Europe Presents Significant Potential Market Opportunity**

# US Market by Disease – Device and Drug Combination

Liver Metastasis	Potential Market # Patients	Potential Market # Procedures	Potential Market (\$MM)**
Ocular Melanoma	1,685	4,213	\$ 105
Cutaneous Melanoma	7,023	17,557	\$ 439
<b>TOTAL MELANOMA (Initial Expected Label)</b>	<b>8,708</b>	<b>21,770</b>	<b>\$ 544</b>
CRC	19,861	49,653	\$ 1,241
HCC (Primary)	5,586	13,964	\$ 349
NET	8,212	20,530	\$ 513
<b>OTHER TOTAL (Potential Label Expansion)</b>	<b>33,659</b>	<b>84,147</b>	<b>\$ 2,104</b>
<b>TOTAL</b>	<b>42,367</b>	<b>105,917</b>	<b>\$ 2,648</b>

Sources: LEK Consulting, GLOBOCAN, Company estimates

1. Assume 2.5 treatments per patient
2. Estimated ASP of \$25K

# APAC Market by Disease

	China	S. Korea (Device)	Japan (Device)	Taiwan (Device)	Australia (Device)	Total Potential (patients)	Potential Market (\$MM) <sup>1,2</sup>
<b>Total Potential Market #Patients</b>							
<b>HCC (Primary)</b>	<b>85,780</b>	<b>3,258</b>	<b>8,296</b>	<b>2,152</b>	<b>263</b>	<b>99,749</b>	<b>\$ 1,156</b>
<b>Other</b>							
<b>CRC</b>	31,127	3,245	14,298	1,441	2,031	<b>52,143</b>	<b>\$ 642</b>
<b>NET</b>	29,197	1,048	2,759	500	462	<b>33,966</b>	<b>\$ 393</b>
<b>Ocular Melanoma</b>	1,765	66	175	31	96	<b>2,134</b>	<b>\$ 25</b>
<b>Cutaneous Melanoma</b>	382	43	136	246	1,144	<b>1,951</b>	<b>\$ 23</b>
<b>OTHER TOTAL</b>	<b>62,472</b>	<b>4,403</b>	<b>17,368</b>	<b>2,218</b>	<b>3,733</b>	<b>90,194</b>	<b>\$ 1,083</b>
<b>TOTAL</b>	<b>148,104</b>	<b>7,661</b>	<b>25,665</b>	<b>4,370</b>	<b>3,996</b>	<b>189,943</b>	<b>\$ 2,239</b>

Sources: LEK Consulting, GLOBOCAN, Company estimates

1. Assume 2.5 treatments per patient
2. Assume ASP of ~\$5K

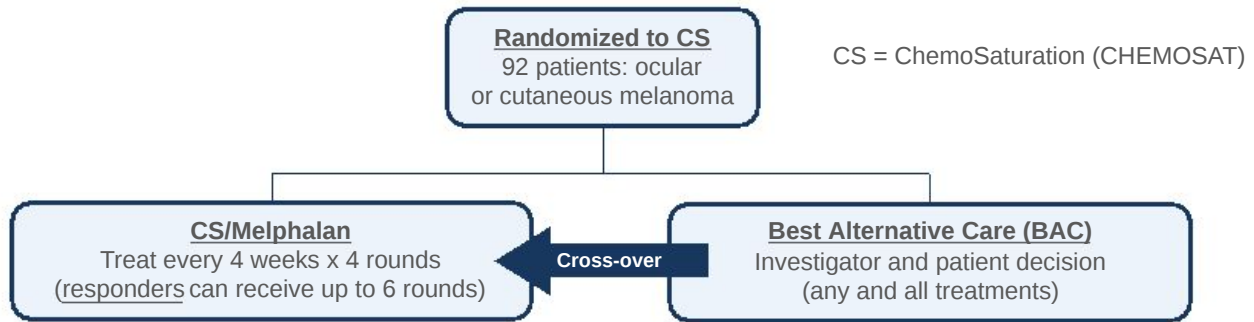
**APAC Target Markets Represent over \$2 Billion Potential Market Opportunity**



## Appendix II

# CHEMOSAT melphalan for metastatic melanoma Phase 3 Pivotal Trial Details

# 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

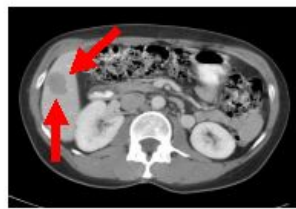
## Secondary Trial Endpoints

- **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**

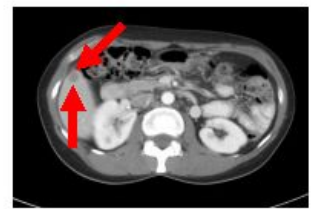
Modeled hPFS for Trial Success:

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

## Hepatic Response – Metastatic Melanoma



Pre-CS (Baseline)



Post-CS (22+ Months)

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



# Positive Phase III Results\*

- **Primary endpoint exceeded, p value = 0.0001, hazard ratio of .35**
  - Treatment arm shows 5x median hepatic progression free (hPFS) survival compared to control arm
  - CS/PHP median hPFS of 8.0 months compared to 1.6 months 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 (9.8 months compared to 9.9 months)
  - CS/PHP median overall PFS of 6.7 months vs 1.6 months for BAC
- **OS exploratory cohort analysis favorable**
  - Median survival of 9.8 months for treatment arm compared to 4.1 months non-crossover BAC patients
  - Median survival of 11.4 months for all patients treated with melphalan, including crossover
  - 9 CS/PHP-treated patients and 3 BAC-treated patients still alive as of 12/2011
- **Safety profile – expected and consistent with currently approved labeling for melphalan**
  - 30-day deaths on PHP: 3/44 patients (6.8%)
    - 1 Neutropenic Sepsis (2.3%); 1 Hepatic Failure 2.5% (95% tumor burden); 1 gastric perforation
  - 30-day deaths on BAC: 3/49 patients (6.1%)

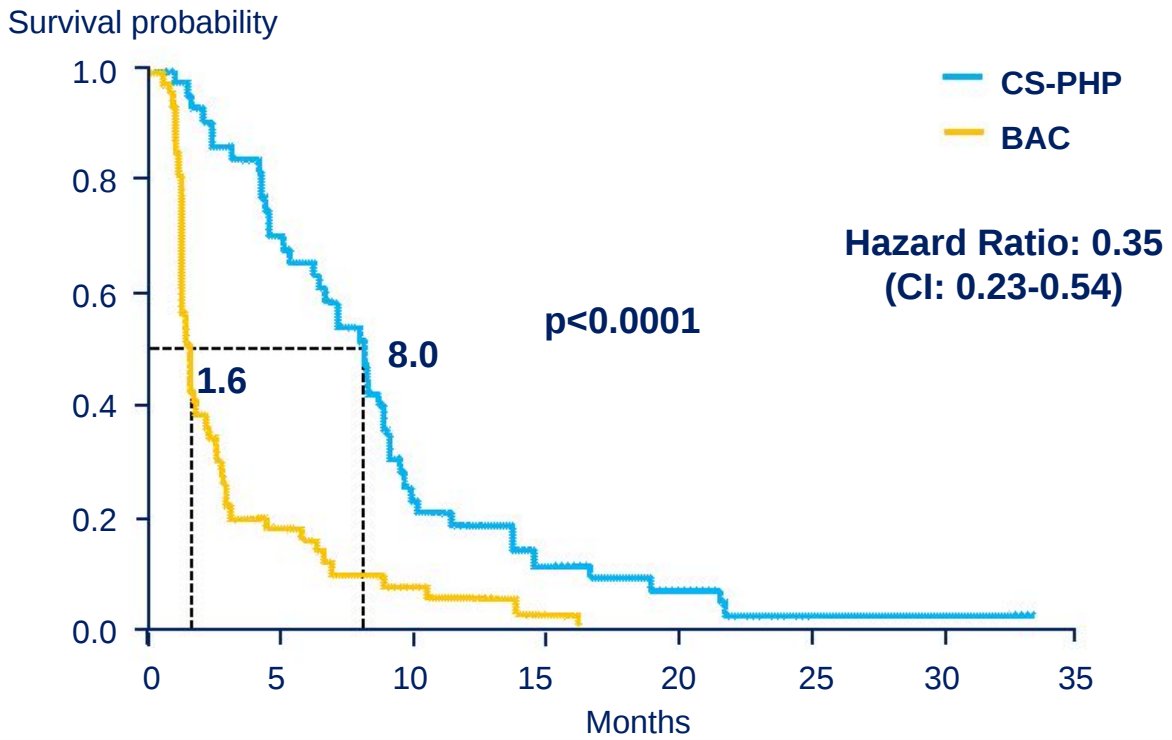
\* Updated Investigator results presented at 2011 ECCO/ESMO Annual Meeting

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

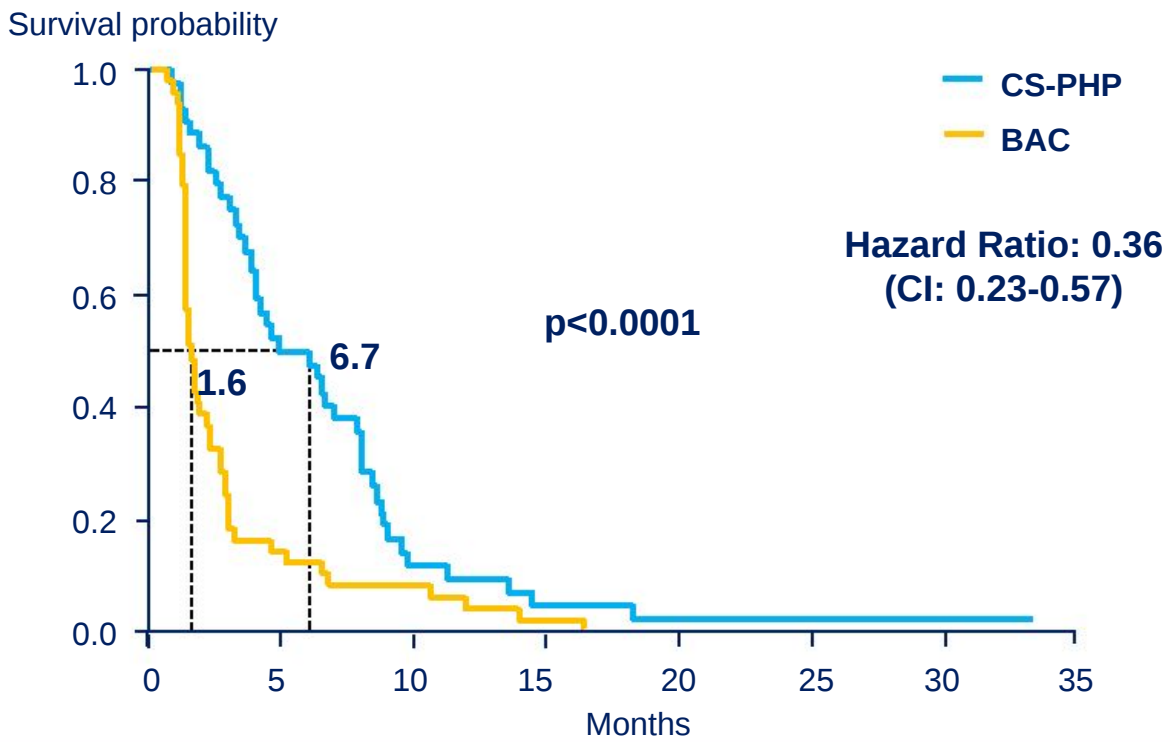
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# Phase 3 Hepatic Progression-free Survival (ITT)



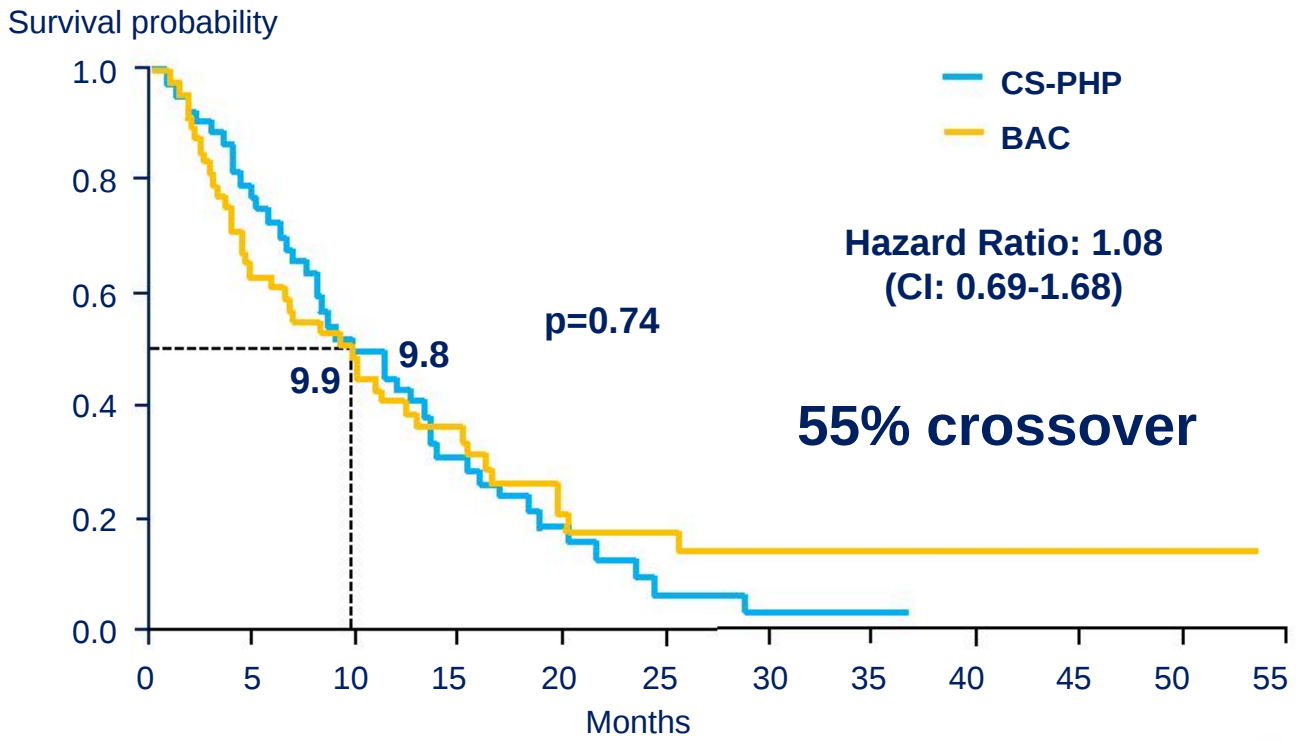
CS-PHP Demonstrated A 5x Improvement In Primary Endpoint of hPFS

# Phase 3 Overall Progression-free Survival (ITT)



CS Also Demonstrated A Highly Statistically Significant Improvement In Overall PFS

# Phase 3 Overall Survival (ITT)



Overall Survival Confounded By Crossover Study Design



## **Appendix III**

# Published Phase I/II Studies of Doxorubicin with PHP (percutaneous hepatic perfusion) For HCC

# Phase I/II Studies of PHP-Doxorubicin For HCC

No. of pts	No. of PHP/ pt	Disease stage (tumor diameter)	Treatment	Median survival (mo)	Response Rates	Reference
HCC (n=79)	1-4	IV A: n=66 IV B: n=13	Doxorubicin 60-150 mg/m <sup>2</sup> Cisplatin 50-150 mg/m <sup>2</sup>	16	HCC pts RR 64.5%	Kobe <sup>1</sup> Phase I/II
CHM (n=23)	1-2	All multiple bilobar Extrahepatic disease in 52%	Mitomycin C 50-200 mg/m <sup>2</sup>	13	5-year survival 20.3%	
HCC (n=11)	1-3	Mean 9.5 cm	Doxorubicin 60-120 mg/m <sup>2</sup>	6.5 13 (responders) 2 (non-responders)	RR 20%	MDACC <sup>2</sup> Phase I
HCC (n=5) CHM (n=8) Other (n=8)	2-4	Extrahepatic disease in 17%	Doxorubicin 50-120 mg/m <sup>2</sup> 5-FU 1000-5000 mg/m <sup>2</sup>	NR	RR 22%	Yale <sup>3</sup> Phase I
HCC (n=7) Other (n=11)	1-10	NR	Doxorubicin 90-120 mg/m <sup>2</sup>	23 (responders) 8 (non-responders)	RR 58%	Yale <sup>4</sup> Phase I

1. Ku Y et al. Chir Gastroenterol 2003;19:370-376
2. Curley SA et al. Ann Surg Oncol 1994;1:389-99
3. Ravikumar TS et al. J Clin Oncol 1994;12:2723-36
4. Hwu WJ et al. Oncol Res 1999;11:529-37

**Delivered Safely In Multiple Studies With Promising Response Rates**

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