

**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): **November 18, 2014**

**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)

1301 Avenue of the Americas, 43<sup>rd</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))
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**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.

DELCATH SYSTEMS, INC.

Dated: November 18, 2014

By: /s/ Barbra Keck  
Name: Barbra Keck  
Title: Vice President, Controller

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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)

November 2014

# Forward-looking Statements

This presentation contains forward-looking statements, within the meaning of the 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 timing and results of future clinical trials including without limitation the OM, HCC, ICC, and mCRC trials in the Company's Clinical Development Program, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system in Europe, our ability to obtain reimbursement for the CHEMOSAT system in various markets including without limitation Germany and the United Kingdom, our ability to successfully commercialize the Melphalan/HDS system and the potential of the Melphalan/HDS system as a treatment for patients with primary and metastatic disease in the liver, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter relating to the ocular melanoma indication and the timing of the same, approval of the Melphalan/HDS system by the US FDA, approval of the current or future Melphalan/HDS system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same, uncertainties relating to the timing and results of research and development projects, and uncertainties regarding our ability to obtain financial and other resources for any clinical trials, research, development, and commercialization activities. These factors, and others, are discussed from time to time 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.

# Why Invest in Delcath?

- We are a clinical company with early commercial activity in Europe focused on cancers of the liver
- Cancers of the liver represent a multi-billion dollar global market and an unmet medical need
- Broad and Informed clinical development program
  - Multiple clinical trials: OM, HCC, ICC
  - Prior FDA experience provides roadmap for clinical programs
- Demonstrated efficacy
  - >225 clinical and commercial patients across multiple tumor types
  - Efficacy and QoL benefit shown as reported by patients and physicians
  - Three recent scientific presentations at ESSO meeting highlighted efficacy and safety
- Demonstrated safety
  - We believe EU commercial experience provides confidence safety can be validated in controlled clinical setting

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Large Market Opportunity, Demonstrated Efficacy, Near-term Value Drivers

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# Near-term Milestones to Create Value

Multiple milestones within next 12 months

- 2014

- o Phase 3 publication submitted by year-end
- o ICC cohort open for enrollment by year-end
- o EU Registry open for enrollment by year-end

- 2015

- o Interim analysis - first 11 HCC patients by mid-year
- o Go/no-go decision on ICC program by mid-year
- o Initiation of Phase 3 ocular melanoma program by mid-year
- o NUB reimbursement decision in Germany by February 1, 2015

- Experienced team to achieve milestones

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Obtaining Data in Multiple Tumor Types

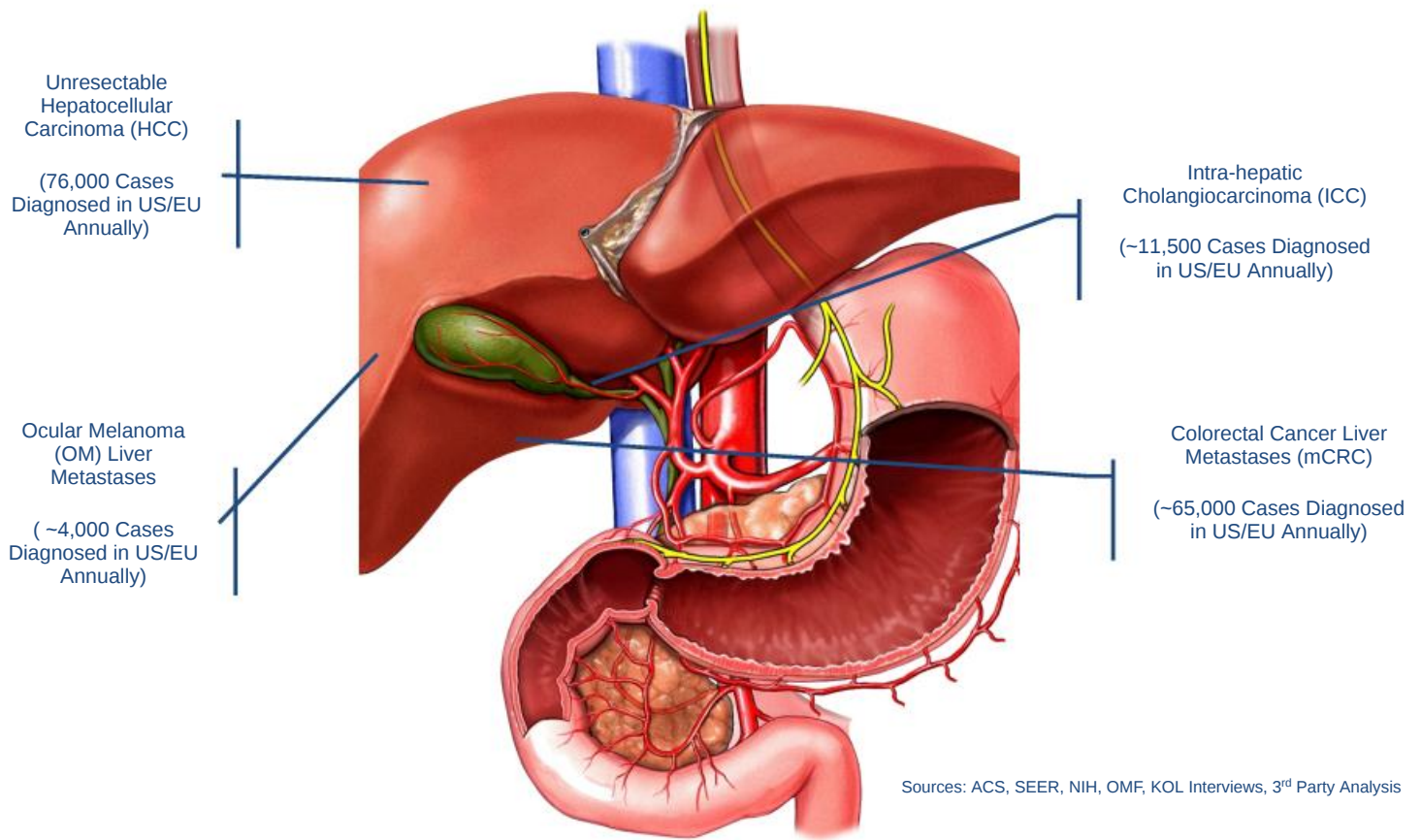
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# The Liver: A Life Limiting Organ

- Cancers of the liver remain a major unmet medical need globally
  - Large global patient population - approximately 1.2 million\* patients 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 - overall survival generally less than 12 months
- CHEMOSAT is a proprietary product uniquely positioned to potentially treat the entire liver as a standalone or complementary therapy

\* SOURCE - 2008 GLOBOCAN

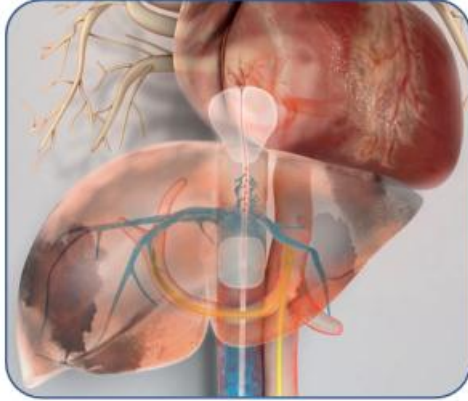
# Potential Applications



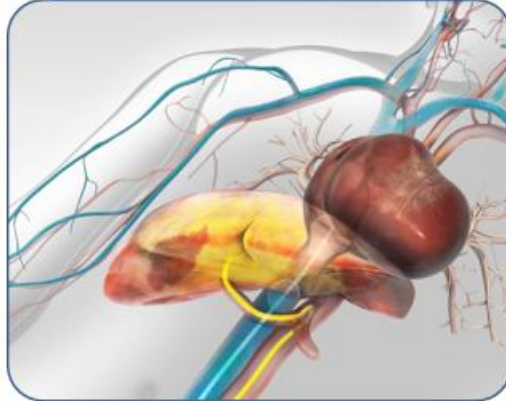
## Liver Cancers: Multi-Billion Dollar Global Market

# The Melphalan Hepatic Delivery System (HDS)

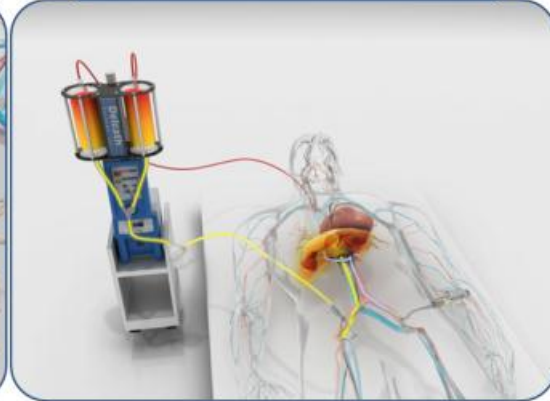
Liver Isolated Via Double Balloon Catheter In IVC



Melphalan Infused Directly Into Liver Via Catheter In Hepatic Artery



Blood Exiting The Liver Filtered By Proprietary Extra-corporeal Filters



- Device designed to administer high dose chemotherapy to the liver while reducing systemic exposure
- Marketed as Delcath Hepatic CHEMOSAT® Delivery System (device only) in EU
- Investigational drug/device combination product regulated as a drug in the US

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>225 Patients Treated In Clinical Development and Initial Commercial Use

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# Broad and Informed Clinical Development Program

## Multiple Clinical Trials

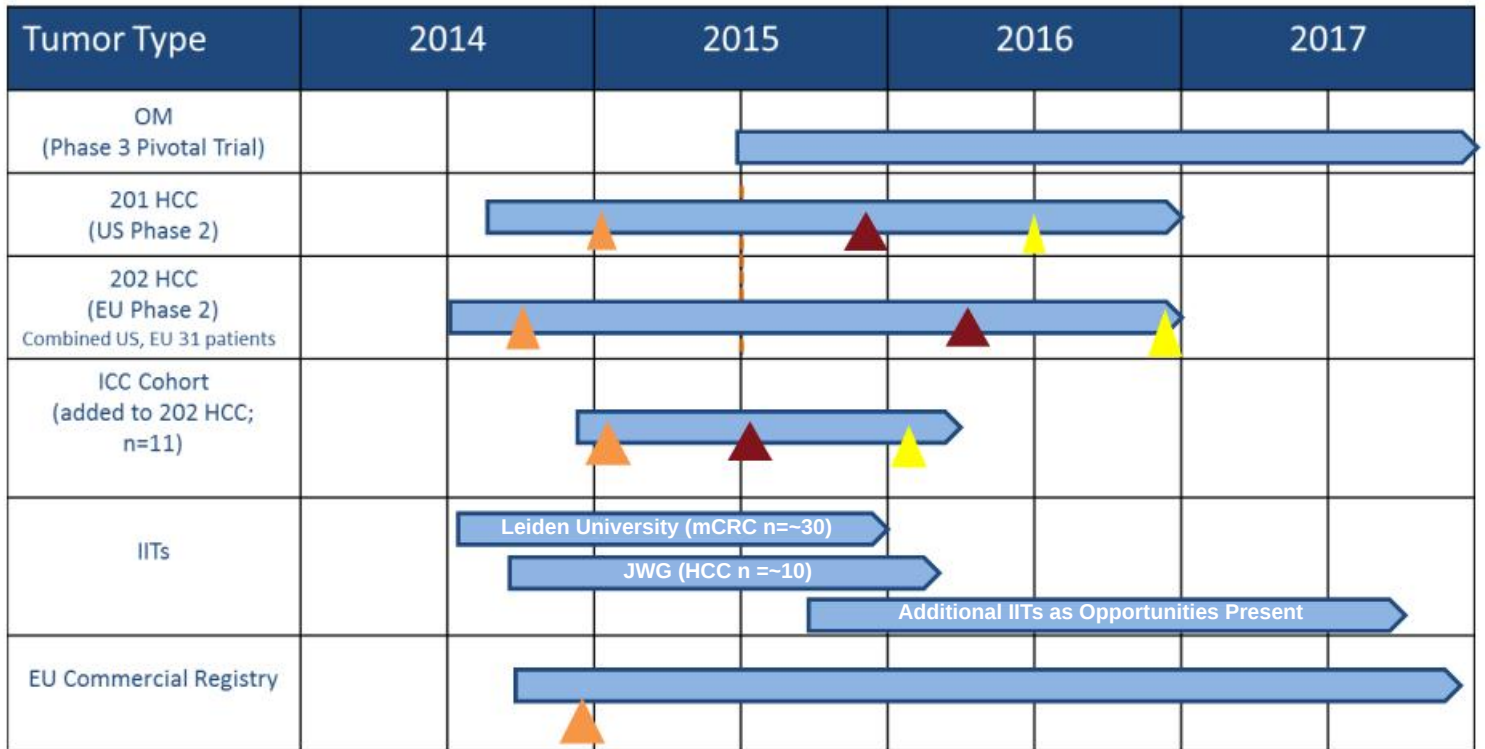
- Initiating plans for Global phase 3 trial in Ocular Melanoma
- (QM) Liver Mets in 2015 for trial start mid year
- Establish Proof of Concept in Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)
  - Commenced Global Phase 2 Program in HCC in 2014
  - Expanding Program to include ICC Cohort in EU Trial
- EU Registry to collect efficacy and safety data in the commercial setting
- Supporting Investigator Initiated Trials (IITs) in HCC & mCRC

# Clinical Development Program at a Glance

| Trials                                 | Tumor                                       | Objectives                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| OM<br>(Phase 3 Pivotal Trial)          | OM liver mets                               | <ul style="list-style-type: none"> <li>▪ Initiating plans for Global phase 3 trial for trial start mid year 2015</li> <li>▪ Primary endpoint: Overall Survival (OS)</li> <li>▪ Believed to be fastest pathway to NDA approval in the US</li> </ul>                                                                                                             |
| Protocol 201<br>(US Phase 2)           | HCC<br>(unresectable confined to the liver) | <ul style="list-style-type: none"> <li>▪ Safety, efficacy of Melphalan/HDS treatment <u>followed by sorafenib</u> <ul style="list-style-type: none"> <li>▪ Evaluate ORR (mRECIST)</li> <li>▪ Assess safety, PFS</li> <li>▪ Characterize systemic exposure of melphalan</li> <li>▪ Assess patient QoL</li> </ul> </li> </ul>                                    |
| Protocol 202<br>(EU Phase 2)           | HCC<br>(unresectable confined to the liver) | <ul style="list-style-type: none"> <li>▪ Safety, efficacy of Melphalan/HDS <u>treatment w/o sorafenib in patients with unresectable liver cancer</u> <ul style="list-style-type: none"> <li>▪ Evaluate ORR (mRECIST)</li> <li>▪ Assess safety, PFS</li> <li>▪ Characterize systemic exposure of melphalan</li> <li>▪ Assess patient QoL</li> </ul> </li> </ul> |
| ICC Cohort<br>(To be added to 202 HCC) | ICC<br>(unresectable confined to the liver) | <ul style="list-style-type: none"> <li>▪ ORR of Melphalan/HDS treatment in patients with intra-hepatic cholangiocarcinoma (ICC) <ul style="list-style-type: none"> <li>▪ Other measures as specified in the 202 EU protocol</li> <li>▪ Signal seeking go/no-go decision by mid 2015</li> <li>▪ Enrollment open by year-end</li> </ul> </li> </ul>              |
| Investigator Initiated Trials (IITs)   | mCRC                                        | University of Leiden study; ~6 patients TX to date                                                                                                                                                                                                                                                                                                             |
|                                        | HCC                                         | Johannes Wolfgang Goethe University Hospital (Frankfurt) study; different patient selection from 202 study; open for enrollment                                                                                                                                                                                                                                |
| EU Commercial Registry                 | EU Commercial Cases                         | <ul style="list-style-type: none"> <li>▪ Data collection on safety, QoL assessments</li> <li>▪ Potential efficacy signals in additional tumor types</li> <li>▪ Support reimbursement in key markets</li> </ul>                                                                                                                                                 |

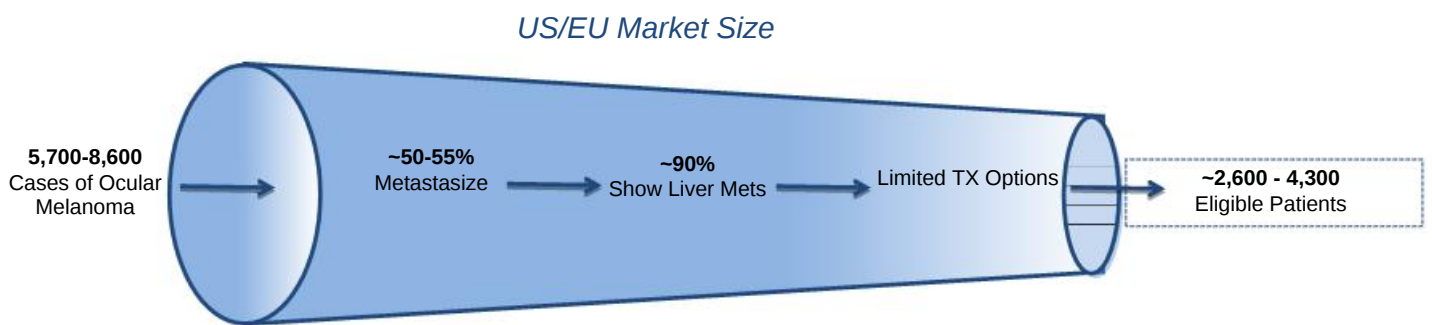
# Clinical Development Program - Timeline

Interim Analysis



# OM Rationale

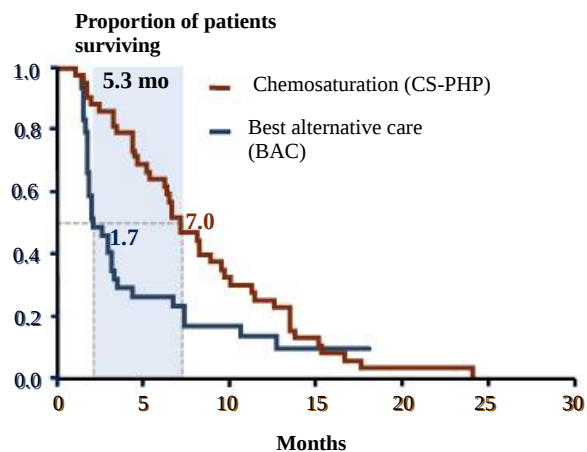
- OM has high incidence of liver metastases
  - Up to 90% of patients with metastases will have liver involvement
  - Life expectancy of approximately 6 months
  - ~7,500 cases of OM liver metastases diagnosed in US and EU annually
- Clear efficacy signal seen in prior P3 trial of Melphalan/HDS
- Currently no standard of care
- Believed to be fastest pathway to NDA approval in the US
- Melphalan/HDS granted orphan drug status by FDA for treatment of patients with OM





# Previous Ocular Melanoma Phase 3 Results

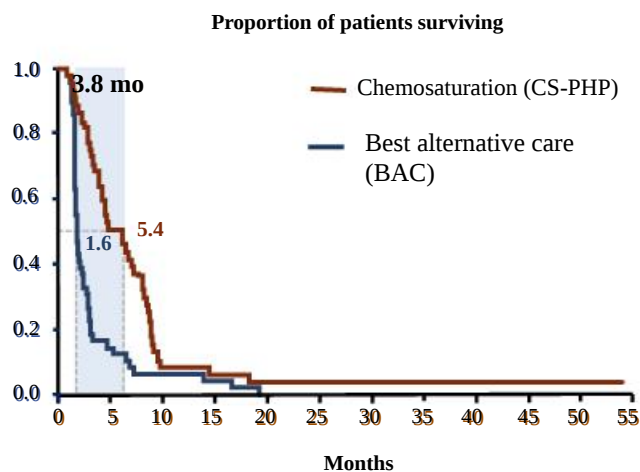
## Hepatic Progression Free Survival (hPFS)



### Intent-to-Treat Analysis (June 2012)

- § 5.3 mos improvement in hPFS
- § Hazard ratio = 0.50
- § (95% CI 0.31-0.80)
- § P=0.0029

## Overall Progression Free Survival (Investigator)

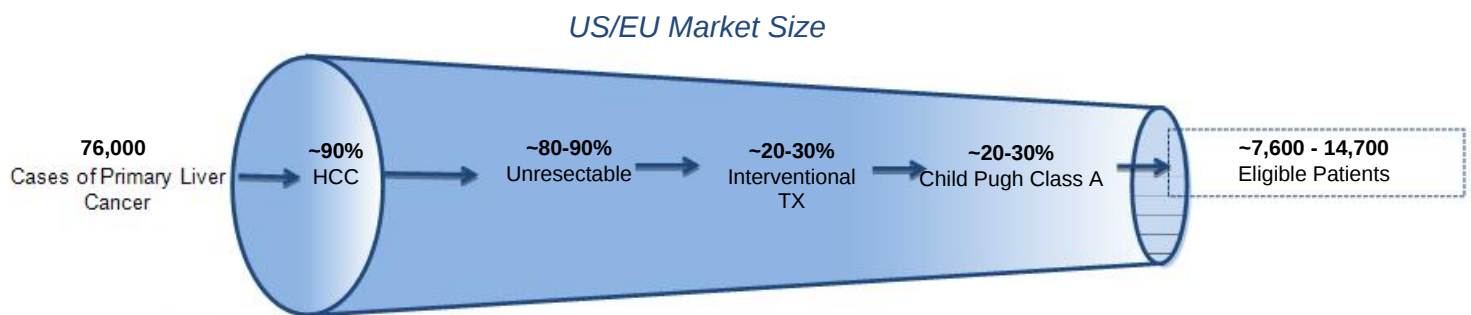


### Intent-to-Treat Analysis (June 2012)

- § 3.8 mos improvement in PFS
- § Hazard ratio = 0.42
- § (95% CI 0.27-0.64)
- § P<0.0001

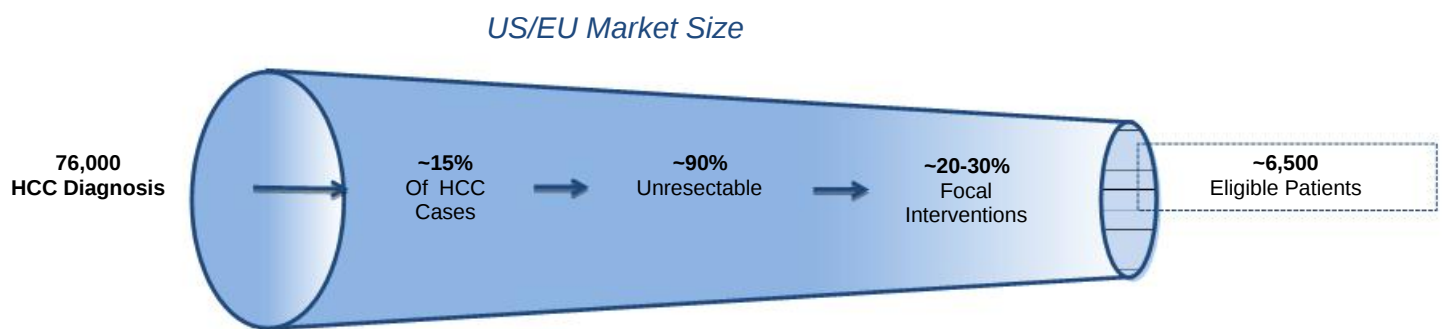
# HCC Rationale

- Significant opportunity in US and EU
  - HCC most common primary cancer of the liver
  - ~76,000\* cases diagnosed annually
- Large unmet medical need in first line therapy
  - Only one currently approved systemic therapy in US, EU, and certain Asian markets
  - ~90% of pts not candidates for surgical resection
  - 20-30% of pts candidates for focal interventions
- Melphalan/HDS granted orphan drug status by FDA for treatment of patients with unresectable HCC



# ICC Rationale

- Significant Market Opportunity in US and EU
  - o ~15% of new HCC cases diagnosed annually
  - o ~90% of patients are not suitable for surgical resection
  - o ~20-30% candidates for focal interventions
  - o Efficacy signals from early commercial uses in EU
- Unmet medical need - Delcath will pursue a melphalan orphan drug designation from the FDA for patients with ICC



## Prior FDA Experience Provides Roadmap for Clinical Programs

- New Drug Application (NDA) submitted August 2012 seeking indication in OM liver metastases
- ODAC meeting in May 2013
  - o Negative Vote
  - o Complete FDA & Delcath ODAC briefing materials available at [www.delcath.com/clinical-research/clinical-bibliography/](http://www.delcath.com/clinical-research/clinical-bibliography/)
- Complete Response Letter (CRL) Issued September 2013
- FDA requests include, but not limited to:
  - o Well-controlled randomized trial(s) to establish the safety and efficacy using the to-be-marketed device configuration
  - o Overall survival as the primary efficacy outcome measure
  - o Demonstrate clinical benefits outweigh risks
- Provides roadmap for clinical studies in any tumor type

## Risks Observed in Previous Clinical Trials

- Risks observed using product and procedure protocol from Previous Clinical Program
- Integrated safety population of patients showed risks associated with Melphalan/ HDS to include:
  - o 4.1% incidence of deaths due to adverse reactions
  - o 4% incidence of stroke
  - o 2% reported incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment
  - o a  $\geq$  70% incidence of grade 4 bone marrow suppression with a median time of recovery of greater than 1 week
  - o 18% incidence of febrile neutropenia, along with the additive risk of hepatic injury, severe hemorrhage, and gastrointestinal perforation
  - o Deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments
  - o Reports from treating physicians in US and EU indicate improved safety profile with improved device and procedure refinements

# Why Do We Believe?

- Improved device and procedure since prior trials
  - o >130 EU treatments
  - o >20 treatments in US Expanded Access Program and Compassionate Use cases
  - o Many issues raised at ODAC have not been reported
- EU patients report improved QoL
- Current device/procedure permitting multiple treatment cycles
- Recent scientific presentations at ESSO for OM from 3 centers in US and EU
  - o University Southampton reported 47% of patients had a partial response and 16% had a complete response
  - o Moffitt reported 67% of patients had a partial response. In addition, one patient was reported to have a complete response
  - o Leiden reported 80% of patients had a partial response

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Patients Benefiting from Melphalan/HDS

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# European Commercialization

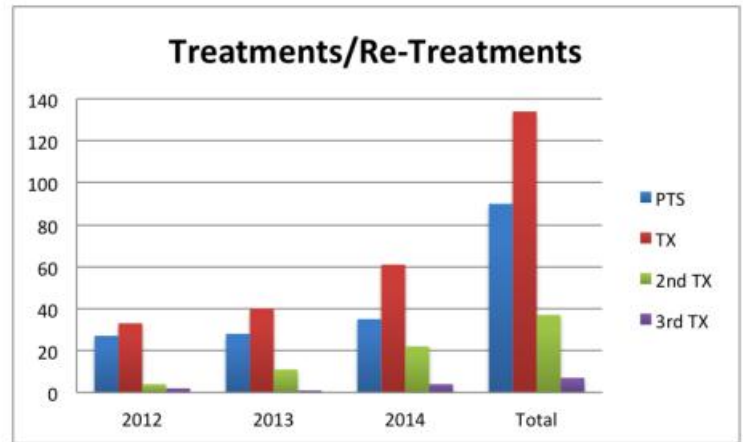
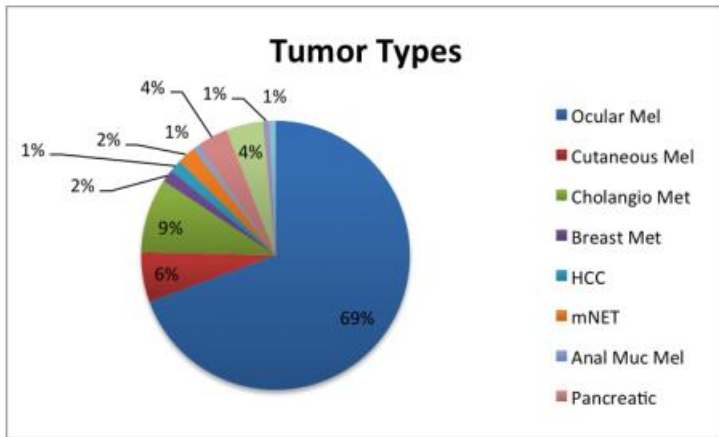


## CHEMOSAT® Hepatic Delivery System

- Approved as Class IIb Medical Device; kit supplied w/o melphalan
- Broad indication for intra-hepatic administration of melphalan hydrochloride and subsequent filtration of the venous blood return
- >130 commercial procedures performed in 15 leading cancer centers in the EU
- Reimbursement via Individual Funding Requests; NUB Value 4 Status in Germany
- Growing Support for NUB Value 1 Status among German KOLs; 2015 NUB decision by February 1, 2015
- UK Block Grants pending & private pay insurance

# CHEMOSAT® Commercial Treatments in Europe

- Multiple Tumor Types Treated Since EU Launch



Treatments/Re-treatments Increasing



# Cash & Capital Resources

**Cash & Cash Equivalents**      **\$23.3 million at September 30, 2014**

**Debt**      **None**

**ATM Program<sup>1</sup>**      **\$40 million available at September 30, 2014**

**Working Capital Line of Credit<sup>2</sup>**      **\$20 million credit facility**

**Shares Outstanding**      **9.4 million (10.5 million fully diluted<sup>3</sup>) at September 30, 2014**

1) Subject to certain limitations

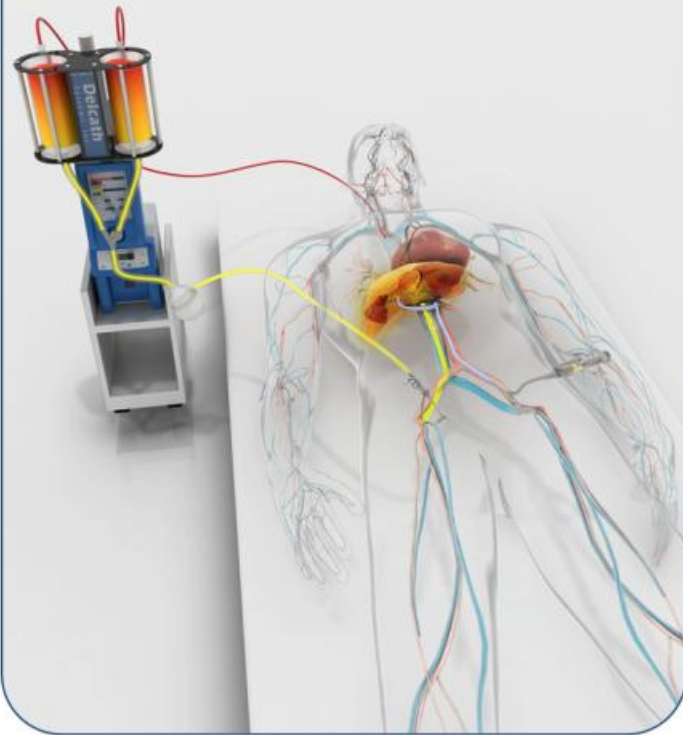
2) Subject to market conditions and certain limitations

3) Fully diluted includes approximate 0.2 million options and 0.9 million warrants

|                            | 2014 Operating Cash Spend (Unaudited) |        |        |         |              |
|----------------------------|---------------------------------------|--------|--------|---------|--------------|
|                            | Q1 A                                  | Q2 A   | Q3 A   | Q4 Est. | FY Est.      |
| <b>Quarterly Guidance</b>  | \$5-6M                                | \$5-6M | \$4-5M | \$4-5M  | \$16.5-17.5M |
| <b>Quarterly Act./Est.</b> | \$4.5M                                | \$4.0M | \$4.0M |         |              |

# Summary

Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS)



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- Cancers of the liver represent a multi-Billion dollar global market and unmet medical need
- Demonstrated efficacy
  - Phase 3 trial
  - Recent presentations at ESSO
- >150 treatments with improved device and procedure in US and EU
- Current device/procedure permitting multiple treatment cycles
- Intend to initiate Phase 3 OM trial 2015
- Phase 2 HCC trial open for enrollment
- ICC cohort to open for enrollment by end 2014
- § Several milestones over next 12 months
- § Experienced team to help achieve milestones in a cost efficient manner

# Concentrating the Power of Chemotherapy™

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# APPENDIX

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# Historic Clinical Program

| Clinical Trials                                | Phase 1                      | Phase 2 | Phase 3                 | Follow Up | EU Commercial Experience |
|------------------------------------------------|------------------------------|---------|-------------------------|-----------|--------------------------|
| Unresectable Hepatic Tumors                    | N=35                         |         |                         |           |                          |
| Unresectable Hepatic Tumors (Multi-Histology)* |                              | N=56    |                         |           |                          |
| Melanoma Liver Metastases                      |                              |         | N=93<br>(44PHP, 49 BAC) |           |                          |
|                                                | Integrated Safety Population |         |                         |           |                          |
| Product Procedure Refinements                  |                              |         |                         |           | N= >90                   |

- Historic Clinical Program demonstrated improvement in hepatic progression free survival in patients with OM
- Positive efficacy signals also seen in HCC, mNET
- Protocol Amendments and Procedure Refinements introduced in response to Adverse Events (AEs) seen on trial
- Reports from treating physicians in US and EU indicate improved safety profile with improved device and procedure refinements

# Publications

- § **Alexander, R., et al.** *Current Status of Percutaneous Hepatic Perfusion as Regional Treatment for Patients with Unresectable Hepatic Metastases: A Review*, *American Oncology and Hematology Review* 2014: 15-23
- § **Vogl, et al.** *Chemosaturation with Percutaneous Hepatic Perfusions of Melphalan for Hepatic Metastases: Experience from Two European Centers*, *Fortschr Röntgestr* 2014
- **H. Schulze-Bergkamen et al.** *Unresectable Isolated Hepatic Metastases from Solid Pseudopapillary Neoplasm of the Pancreas: A Case Report of Chemosaturation with High-Dose Melphalan*, *Pancreatology* 2014
- § **Forster M., et al.** *Chemosaturation with Percutaneous Hepatic Perfusion for Unresectable Metastatic Melanoma or Sarcoma to the Liver: A Single Institution Experience*. *Journal of Surgical Oncology*. 2013
- § **Yamamoto M, Zager J.** *Isolated Hepatic Perfusion for Metastatic Melanoma*. *Journal of Surgical Oncology*. 2013

## 2014 ESSO Congress Presentations

- § *A Single Institution Experience with Percutaneous Hepatic Perfusion for Unresectable Ocular Melanoma and Sarcoma in the Liver*---Moffitt Cancer Center, U.S.; J. Zager
- § *Percutaneous Hepatic Perfusion with Melphalan in Treating Unresectable Liver Metastases from Colorectal Cancer and Uveal (Ocular) Melanoma* - Leiden University Medical Centre (LUMC), The Netherlands; N. de Leede
- § *Initial United Kingdom Experience with Melphalan Percutaneous Hepatic Perfusion (PHP) For Treatment of Inoperable Ocular Melanoma Metastases*---University Hospital Southampton, U.K; B. Stedman