UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): September 3, 2015

Delcath Systems, Inc.
(Exact Name of Registrant Specified in Charter)

Delaware	**001-16133**	**06-1245881**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

1301 Avenue of the Americas, 43rd Floor New York, New York	**10019**
(Address of Principal Executive Offices)	**(Zip Code)**

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

Not Applicable
(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:

☐ 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Delcath Systems, Inc. Investor Presentation Slides

SIGNATURE

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.

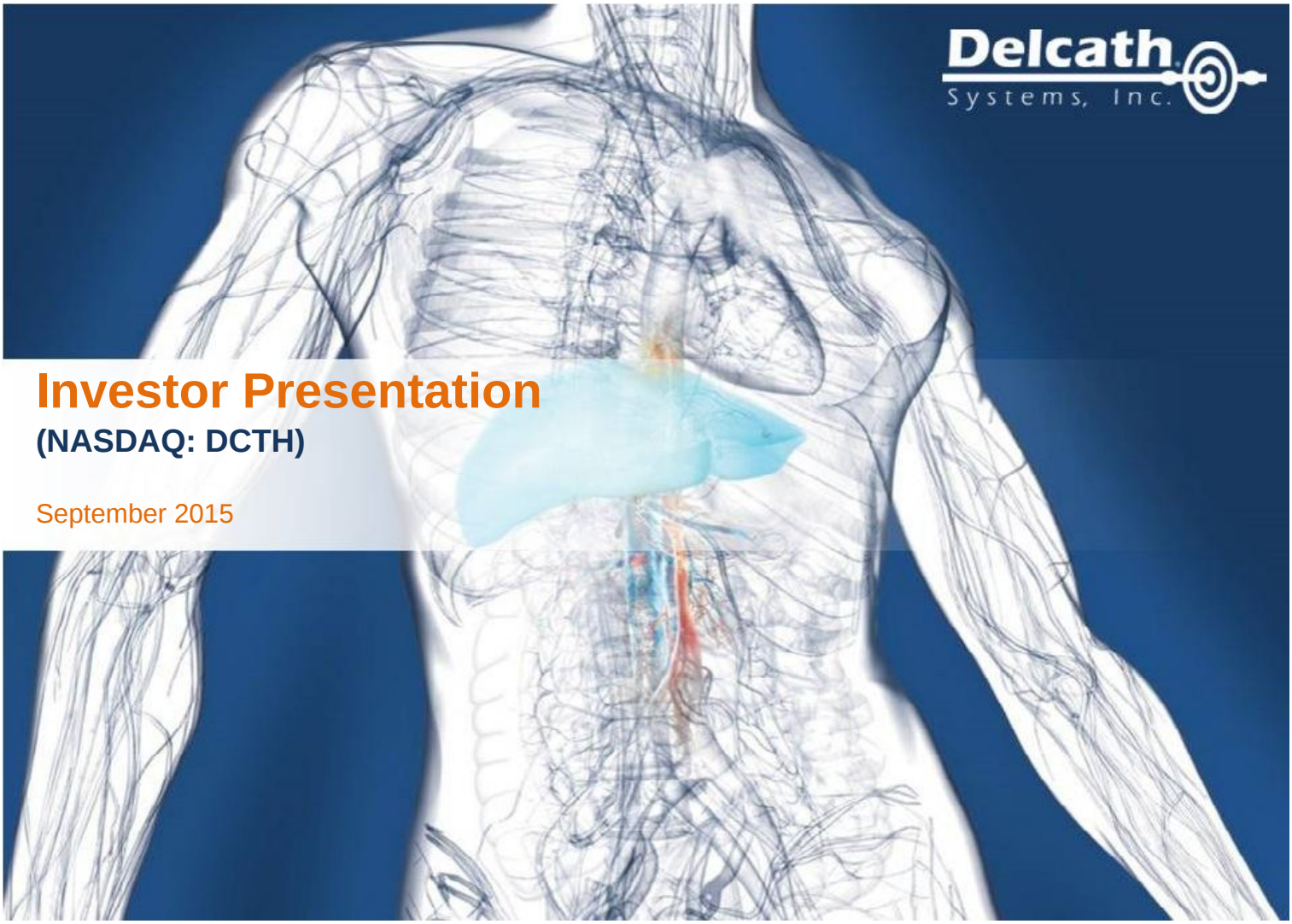
Date: September 3, 2015

By: /s/ Jennifer K. Simpson
Jennifer K. Simpson
President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
99.1	Delcath Systems, Inc. Investor Presentation Slides

Exhibit 99.1



Investor Presentation

(NASDAQ: DCTH)

September 2015

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 U.S. FDA, acceptance of the Phase 3 trial publication, the impact of presentations and abstracts at major medical meetings and congresses (SSO, ASCO, CIRSE, ESMO, EADO, RSNA) and future clinical results consistent with the data presented, approval of the current or future Melphalan/HDS system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the U.S. 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.

About Delcath Systems

- A specialty pharmaceutical and medical device oncology company with a principal therapeutic focus on the treatment of primary liver cancer and other cancers that have metastasized to the liver
- Proprietary system isolates the liver from circulation, delivers a substantially higher concentration of chemotherapy (melphalan) compared with systemic doses, and filters most of the chemotherapy out of the blood prior to returning it to the patient
- In late-stage clinical development in the U.S. with initial commercial activities underway in Europe
- Initially pursuing orphan indications in metastatic ocular melanoma, hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC)

Seeking to Make a Clinically Meaningful Difference For Cancer Patients With Liver Dominant Disease

Investment Highlights

- **Late-stage asset –**clinically meaningful efficacy demonstrated in >600 procedures and in multiple tumor types
- **Active clinical program –** initiating global Phase 3 study in ocular melanoma; HCC/ICC Phase 2 program ongoing
- **Unique, highly differentiated solution –** multiple orphan designations create barriers to entry
- **Early stage commercialization in EU –** >200 procedures performed in EU with 2nd Generation product and protocol
- **Imminent valuation milestones –** 2015 value drivers include publications, reimbursement and clinical data
- **Attractive business model –**initial orphan focus and anticipated high gross margins form basis of profitable long-term model
- **Experienced management team –** aligned with requirements of clinically driven pharmaceutical industry

Large, Compelling Market Opportunity

2014-2015 Milestones

2014 Accomplishments

- ✓ Phase 2 HCC trial open and first patient treated
- ✓ 100th patient treated in Europe (commercial and clinical)
- ✓ Positive efficacy data from three institutions presented at ESSO 2014
- ✓ Product revenue increased 118% Y/Y to $1.1 million
- ✓ Cash burn reduced by 50% Y/Y

1H-2015

- ✓ NUB reimbursement decision in Germany – Value 4 awarded for 2015
- ✓ Submit Phase 3 metastatic melanoma trial results for publication
- ✓ EU registry open for enrollment
- ✓ ICC cohort open for enrollment

2H-2015

- Initiation of global Phase 3 metastatic ocular melanoma program
- Interim evaluation on HCC/ICC program

Executing on Multiple Fronts to Create Value

The Liver: A Life-Limiting Organ

- Cancers of the liver remain a major unmet medical need
  - 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, with overall survival generally less than 12 months
- CHEMOSAT® Melphalan/HDS is a proprietary product uniquely positioned to potentially treat the entire liver as a standalone or complementary therapy

Effective Liver Cancer Treatment Remains a Major Unmet Medical Need

* SOURCE – 2008 GLOBOCAN

Our Solution

- Our proprietary system isolates the liver circulation, delivers a high concentration of chemotherapy (melphalan) and filters most of the chemotherapy out of the blood prior to returning it to the patient

- The procedure typically takes approximately 2-3 hours to complete and involves a team including the interventional radiologist, oncologist, anesthesiologist and perfusionist

- We believe more than 200 treatments with improved device and procedure provide confidence safety can be validated in a controlled setting

Whole Organ-Focus Disease Control

Existing Liver Cancer Treatments Landscape

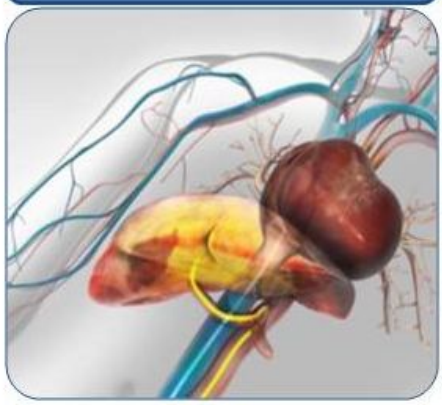
Treatment	Advantages	Disadvantages
Systemic	– Non-invasive – Repeatable	– Systemic toxicities – Limited efficacy in liver
Regional (e.g., Isolated Hepatic Perfusion)	– Therapeutic effect – Targeted	– Invasive/limited repeatability – Multiple treatments are required but not possible
Focal (e.g., surgery, radioembolization, chemoembolization, radiofrequency ablation)	– Partial removal or treatment of tumors	– Only 10%-20% are resectable – Invasive and/or limited repeatability – Treatment is limited by tumor size, number of lesions and location – Tumor revascularization – **Cannot treat diffuse disease**

Existing Liver Cancer Treatments Have Limitations

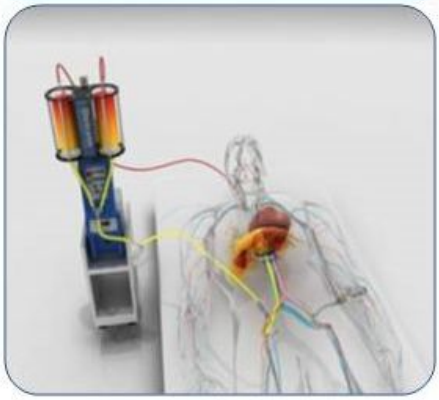
The Melphalan Hepatic Delivery System (HDS)

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 U.S.

Improved Product & Procedure in Use Since 2012

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
Melphalan/HDS (PHP)	**3.00**

- Well-understood, dose-dependent, tumor-preferential, alkylating cytotoxic agent that demonstrates little to no hepatic toxicity
- Dose administered directly to liver is substantially higher than that of systemic IV chemotherapy
- Melphalan, an established chemotherapy agent, is proven active at high doses with broad antitumor activity

An Established Drug for Liver Cancer Therapy

Total Available EU & U.S. Market Opportunity

Cancer Type	Annual Incidence[1]	Eligible Pts[2]	Annual Potential Market Opportunity (millions)[3,5]	Annual Potential Market Opportunity (millions)[4,5]
Ocular Melanoma (OM)	5,700-8,600	2,600-4,300	$104-$215	$208-$430
Cholangio Carcinoma (ICC)	11,500	6,500	$260-$330	$520-$660
Hepatocellular Carcinoma (HCC)	64,500	7,600-14,700	$304-$735	$608-$1,470
Colorectal (CRC)	411,000	40,000-55,000	$1,600-$2,750	$3,200-$5,500
Total EU and US	492,700-495,600	56,700-80,500	$2,268-$4,030	$4,536-$8,060

Notes:

1) Source: Globocan, American Cancer Society

2) Source: LEK, Strategy&, Company estimates

3) Assumes an average of two treatments per patient

4) Assumes an average of four treatments per patient

5) Assumes $20,000-$25,000 USD per treatment

Cancers Of The Liver Remain a Multibillion-Dollar Unmet Medical Need

European Commercial Activity

CHEMOSAT®
Hepatic Delivery System

- Approved as Class IIb Medical Device; kit supplied without melphalan
- Broad indication for intra-hepatic administration of melphalan hydrochloride and subsequent filtration of the venous blood return
- >200 commercial procedures performed in leading cancer centers across the EU
- Reimbursement via Individual Funding Requests; NUB Value 4 Status in Germany
- UK private pay insurance; block grants pending
- 2015 YTD EU Sales exceed 2014 on local currency basis

Growing Body of Clinical Support for CHEMOSAT

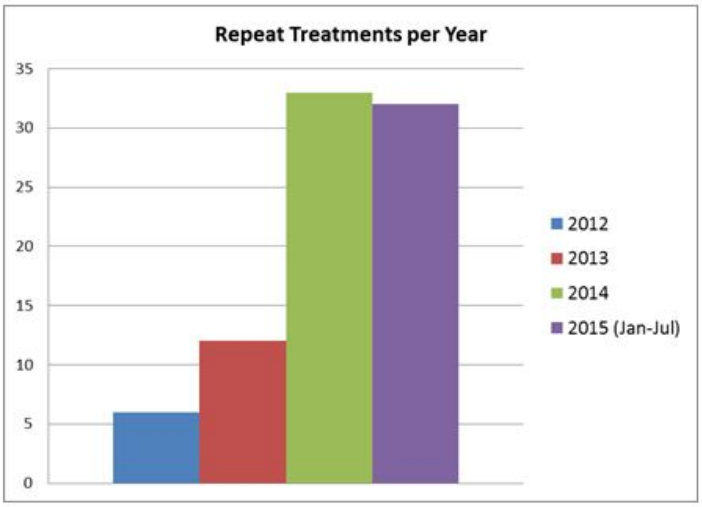
EU KOL Forum affirms benefits to liver cancer patients

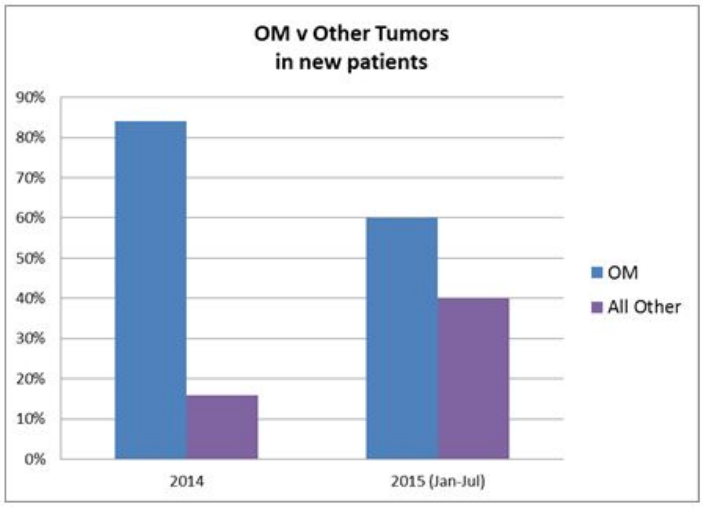
- ≤4 TX being administered; shown to be safe and well tolerated
- Providing clinical benefit and good QoL
- Reimbursement continues to be covered through individual funding requests

Abstracts Accepted at Major Medical Meetings

- ESSO 2014
- SSO 2015
- ASCO 2015
- CIRSE 2015
- EADO 2015
- ESMO 2015
- RSNA 2015

Increasing & Expanding Clinical Utilization





Utilization Expanding Into Other Tumor Types Beyond Ocular Melanoma

Clinically Differentiated Results

- Phase 1, 2 and 3 trials produced positive results in multiple histologies
- Melanoma Liver Mets
  - Positive Phase 3 results in hepatic metastatic melanoma
  - n=93 (90% ocular melanoma, 10% cutaneous melanoma)
- Neuroendocrine Tumor (NET) Liver Mets
  - mNET cohort in Phase 2 trial showed encouraging 42% objective response rate (ORR) vs. ~10% for approved targeted therapy
  - Median overall survival of ~32 months on ITT basis
- Hepatocellular Carcinoma (HCC)
  - Positive signal with high-dose melphalan in HCC cohort of Phase 2 trial (5/8 patients) is encouraging when approved systemic therapies have modest efficacy and challenges with tolerability
- Colorectal Cancer (CRC) Liver Mets
  - Data from surgical Isolated Hepatic Perfusion (IHP) with melphalan indicates strong potential in well-defined patient population with earlier stage CRC yielding ~50-60% median response rate and median OS of 17.4-24.8 mos

Encouraging Initial Results on a Broad Range of Histologies

Clinical Development Program

Trials	Tumor	Objectives
Phase 3 Pivotal Trial	OM liver mets	▪ Global Phase 3 trial to start 2H-2015 ▪ Primary endpoint: Overall Survival (OS) ▪ Believed to be fastest pathway to NDA approval in the U.S.

Phase 2 Program	HCC (unresectable confined to the liver)	▪ Protocol 201 (U.S. only)
		▪ Safety, efficacy of Melphalan/HDS treatment followed by sorafenib
		  ▪ Evaluate ORR (mRECIST)
		  ▪ Assess safety, PFS
		  ▪ Characterize systemic exposure of melphalan
		  ▪ Assess patient QoL

		▪ Protocol 202 (EU only)
		▪ Safety, efficacy of Melphalan/HDS treatment w/o sorafenib in patients with unresectable liver cancer
		  ▪ Evaluate ORR (mRECIST)
		  ▪ Assess safety, PFS
		  ▪ Characterize systemic exposure of melphalan
		  ▪ Assess patient QoL

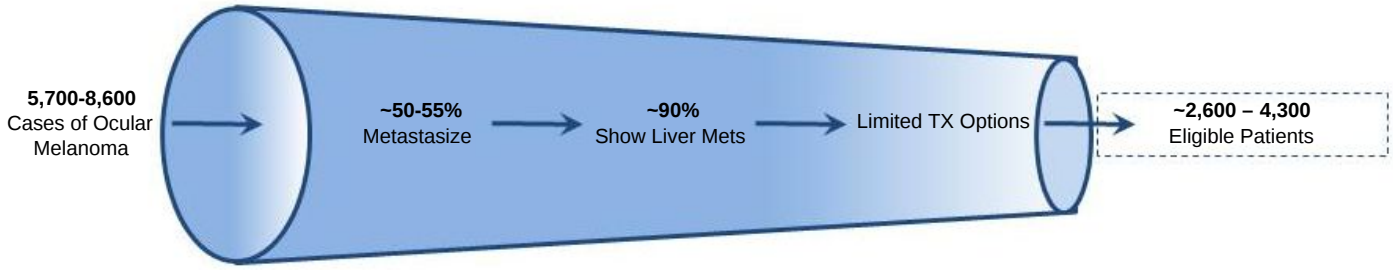
	ICC (unresectable confined to the liver)	▪ Added to 202 HCC trial protocol
		▪ ORR of Melphalan/HDS treatment in patients with intra-hepatic cholangiocarcinoma (ICC)
		  ▪ Other measures as specified in the 202 EU protocol
		  ▪ Signal-seeking go/no-go decision 2H-2015

Investigator Initiated Trials	mCRC	▪ University of Leiden study; 10 patients treated 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	▪ Open for enrollment; data collection on safety, QoL assessments ▪ Potential efficacy signals in additional tumor types ▪ Support reimbursement in key markets

OM Metastases 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
  - 5,700 - 8,600 cases of OM liver metastases diagnosed in U.S. and EU annually
- Clear efficacy signal seen in prior Phase 3 trial of Melphalan/HDS
- Currently no standard of care
- Believed to be fastest pathway to NDA approval in the U.S.
- FDA granted Melphalan/HDS orphan drug designation for treatment of OM

U.S./EU Market Size

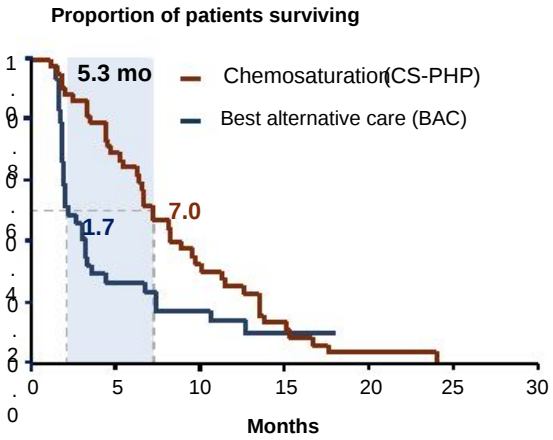


Proven Efficacy in Attractive Orphan Opportunity

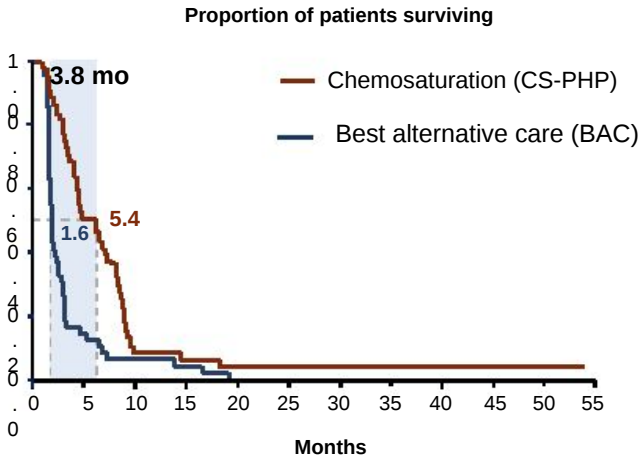
*Sources: ACS, SEER, NIH, OMF, KOL Interviews, 2014 3rd Party Analysis

Previous Ocular Melanoma Mets Phase 3 Results

Hepatic Progression Free Survival (hPFS)



Overall Progression Free Survival (Investigator)



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

4 subjects remain alive at 5-8 years
All were recipients of CS-PHP

Intent-to-Treat Analysis (June 2012)

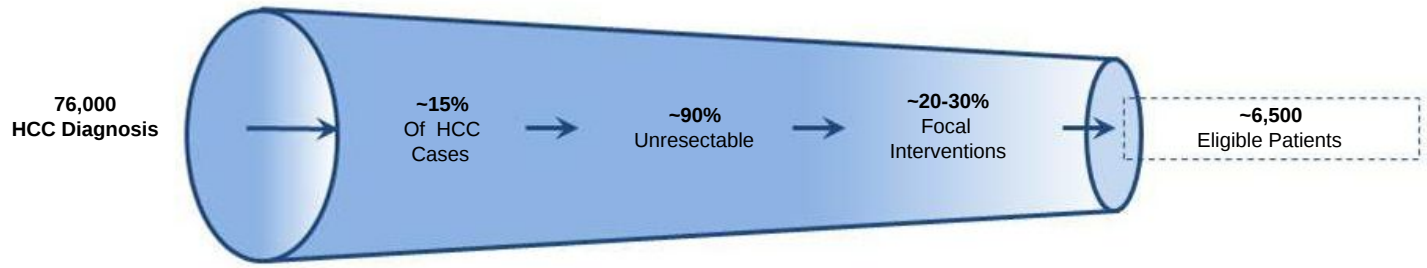
- 3.8 mos improvement in PFS
- Hazard ratio = 0.42
- (95% CI 0.27–0.64)
- p<0.0001

Clinically Meaningful Benefit Previously Demonstrated for Metastatic OM Patients

ICC Rationale

- Significant market opportunity in U.S. and EU
  - ~15% of new HCC cases diagnosed annually
  - ~90% of patients are not suitable for surgical resection
  - ~20-30% are candidates for focal interventions
  - Efficacy signals from early commercial uses in EU
- Unmet medical need – FDA granted melphalan orphan drug designation for patients with ICC

U.S./EU Market Size



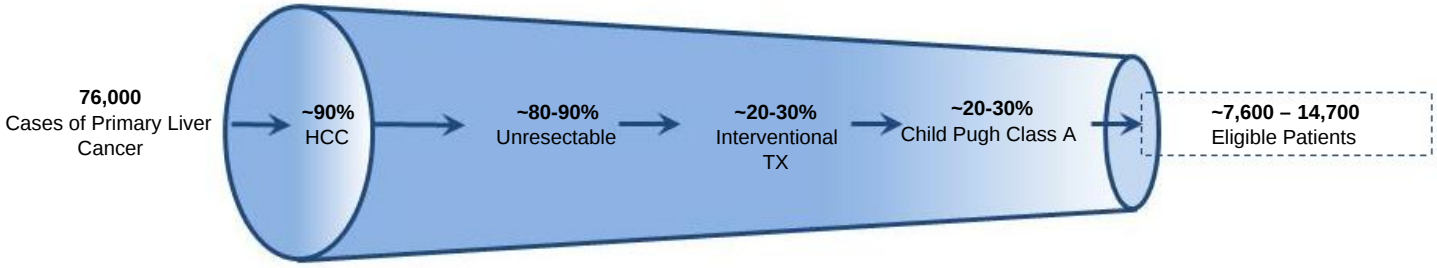
Encouraging Early Commercial Activity in Disease With Limited Treatment Options

*Sources: ACS, SEER, NIH, KOL Interviews, 2014 3rd Party Analysis

HCC Rationale

- Significant opportunity in the U.S. 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 approved systemic therapy in the U.S., EU and certain Asian markets
  - ~90% of patients not candidates for surgical resection
  - 20-30% of patients are candidates for focal interventions
- FDA granted Melphalan/HDS orphan drug designation for treatment of unresectable HCC

U.S./EU Market Size



Large, Deadly Disease in Need of Better Treatments

*Sources: WHO,KOL Interviews, 2014 3rd Party Analysis

Prior FDA Experience

- New Drug Application (NDA) submitted August 2012 seeking indication in OM liver metastases with first-generation filter and procedure
- ODAC meeting in May 2013
  - Efficacy shown with statistical significance
  - Negative vote due to benefit/risk analysis
  - Complete FDA & Delcath ODAC briefing materials available at www.delcath.com/clinical-research/clinical-bibliography/
- Complete Response Letter (CRL) issued September 2013
- FDA requests include, but not limited to:
  - Well-controlled randomized trial(s) to establish the safety and efficacy using the to-be-marketed device configuration
  - Overall survival as the primary efficacy outcome measure
  - Demonstrate clinical benefits outweigh risks

FDA Learnings Provide Beneficial Clinical Study Roadmap

Risks Observed in Previous Clinical Program

- ***Risks observed with prior product and procedure protocol***
- Integrated safety population of patients showed risks associated with melphalan/HDS included:
  - 4.1% incidence of death due to adverse reactions
  - 4% incidence of stroke
  - 2% reported incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment
  - ≥ 70% incidence of grade 4 bone marrow suppression with a median time of recovery of greater than 1 week
  - 18% incidence of febrile neutropenia, along with the additive risk of hepatic injury, severe hemorrhage and gastrointestinal perforation
- Deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments

Treating Physicians in U.S. and EU Report Improved Safety Profile

Safety Improvements Implemented

- New generation filter
  - Improve filter efficiency and consistency
- Vasopressors and methylprednisolone
  - Reduce cardiovascular risk
- Prophylactic transfusions and growth factors
  - Reduce risk of myelosuppression
- Intra-arterial nitroglycerin
  - Prevent hepatic arterial spasm
- Liver tumor burden not to exceed >50%
  - Address risk of liver failure

Decisive Measures to Assure Improved Safety

Recent Data Presentations - ASCO 2015

- Analysis of 20 ocular melanoma patients who received 34 treatments at Southampton University Hospital
  - Eleven patients remain alive after a median of 280 days with one complete response ongoing at >1 year
  - From the diagnosis of liver metastases, 11 patients (55%) survived to one year and 3 (15%) for >2 years; no procedure related deaths were seen
  - ORR 85%: 2 patients (10%) demonstrated stable disease for >3 months, 13 patients (65%) had a partial response, 2 patients (10%) demonstrated complete response
  - Nine deaths from disease progression occurred after a median of 264 days from the first procedure
- Adverse Events
  - Early AEs often expected with percutaneous hepatic perfusion (PHP) were observed including coagulopathy, electrolyte disturbances and transient transaminases (elevated liver enzymes). Rare late AEs (1 patient each) included hair loss, skin rash, myelosuppression and persistent transaminases (elevated liver enzymes)
  - AEs seen were grade 1 (n=12), 2 (n=13), 3 (n=5) and 4 (n=1)
  - Grade 4 complication was pulmonary edema due to fluid overload

Recent Data Presentations - SSO 2015

- Moffitt Cancer Center (Tampa, FL)
  - Retrospective analysis of 30 patients with ocular or cutaneous melanoma treated with Melphalan/HDS (n=10), chemoembolization (CE, n=12), and yttrium-90 (Y90, n=6)
  - Study showed significant difference in hepatic progression free survival (HPFS) for Melphalan/HDS (310 days), CE (80 days), Y-90 (54 days)
  - Median overall survival (OS) longest for Melphalan/HDS (736 days) vs Y90 (285 days) CE (265 days), but did not reach statistical significance
  - Authors concluded that HPFS and progression free survival (PFS) were significantly prolonged with Melphalan/HDS vs CE and Y90
- Additional abstracts accepted for presentation at CIRSE, ESMO, EADO & RSNA in fall 2015

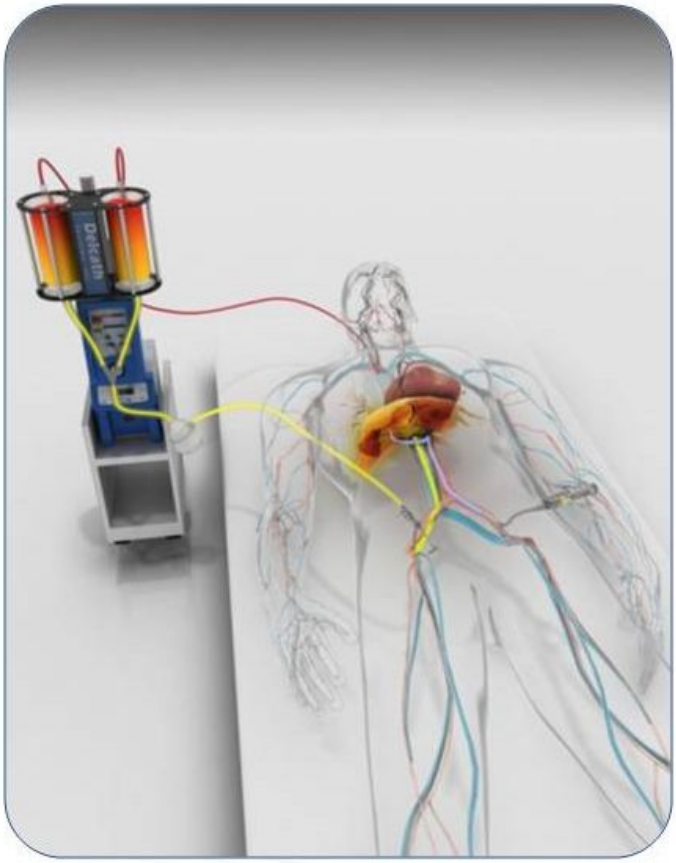
Cash & Capital Resources

Cash & Cash Equivalents	**$19.1 million at July 31, 2015**
Debt	**None**
ATM Program [1]	**$40 million available at July 31, 2015**
Shares Outstanding	**21.8 million (40.7 million fully diluted[2]) at July 31, 2015**

1) Subject to market conditions and certain limitations
2) Fully diluted includes approximately 0.8 million options and 18.1 million warrants

Focused Spending and Resources to Support Execution of Near-term Plan

In Summary



- *Attractive multi-billion dollar orphan drug business model*
- *Unique, highly differentiated solution*
- *Late-stage asset in U.S. with active clinical development program*
- *Early commercial activity in EU with increasing sales/procedure volumes*
- *Compelling emerging data*
- *Imminent valuation milestones*
- *Experienced pharmaceutical management team executing a data-driven plan*

Concentrating the Power of Chemotherapy™

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