
**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 2, 2015

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, 43rd 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.

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 2, 2015

By: /s/ Peter J. Graham

Name: Peter J. Graham

Title: Executive Vice President, General Counsel

EXHIBIT INDEX

Exhibit No.

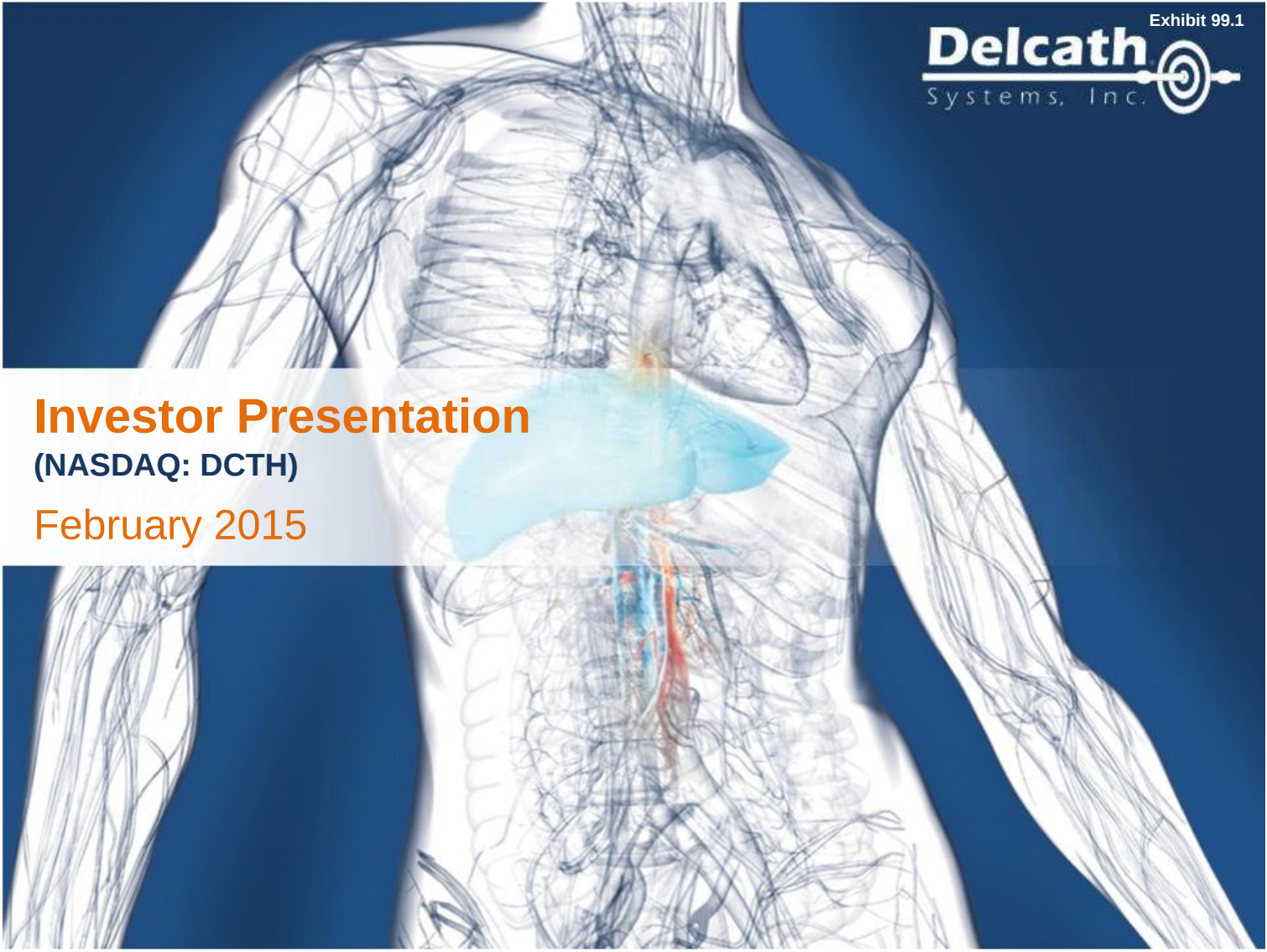
Description

99.1 Delcath Systems, Inc. Investor Presentation Slides

Investor Presentation

(NASDAQ: DCTH)

February 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 US FDA, submission and acceptance of the phase 3 trial publication, 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.

Delcath at a Glance

- A late-stage clinical company with early commercial activity in Europe
- CHEMOSAT is approved as a medical device (CE Mark) in Europe; investigational new combination product in U.S. for treating cancers of the liver
- Focused clinical development program initially pursuing orphan indications in metastatic ocular melanoma and primary liver cancer
- Based in New York with European operations in Galway, Ireland
- Traded on NASDAQ under symbol DCTH
- More than \$23 million in cash at 9/30/2014

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

Investment Highlights

Large market opportunity - cancers of the liver remain a multi-billion dollar unmet medical need

Unique, highly differentiated solution – orphan designations create barriers to competitive entry

Late-stage, asset - demonstrated clinically meaningful efficacy in over 550 procedures and multiple tumor types

Compelling emerging data – demonstrated early success in multiple tumor types

Imminent valuation milestones - 2015 value drivers include publications, reimbursement & clinical data

Attractive business model - initial orphan focus and anticipated high gross margins form basis of profitable long-term model

Experienced management team - now aligned with requirements of clinically driven pharmaceutical industry

We Believe We are Positioned to Capitalize on Large, Compelling Market Opportunity

2014-2015 Milestones

2014 Accomplishments

- o Phase 2 HCC trial open and first patient treated
- o 100th patient treated in Europe (commercial and clinical)
- o Positive efficacy data from three institutions presented at ESSO 2014
- o Q3 sales increased 201% Y/Y to \$217K
- o Cash burn reduced by almost 60% Y/Y through September

1H-2015

- o Submit Phase 3 metastatic melanoma publication
- o EU Registry open for enrollment
- o ICC cohort open for enrollment
- o NUB reimbursement decision in Germany — Value 4 awarded for 2015

2H-2015

- o Interim analysis on HCC patients
- o Initiation of phase 3 ocular melanoma program

Executing on Multiple Fronts to Create Value

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/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

Existing Liver Cancer Treatments Landscape

Treatment	Advantages	Disadvantages
Systemic	<ul style="list-style-type: none">– Non-invasive– Repeatable	<ul style="list-style-type: none">– Systemic toxicities– Limited efficacy in liver
Regional (e.g., Isolated Hepatic Perfusion)	<ul style="list-style-type: none">– Therapeutic effect– Targeted	<ul style="list-style-type: none">– Invasive/limited repeatability– Multiple treatments are required but not possible
Focal (e.g. surgery, radioembolization, chemoembolization, radio frequency ablation)	<ul style="list-style-type: none">– Partial removal or treatment of tumors	<ul style="list-style-type: none">– Only 10% to 20% 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

Our Solution – Whole Organ-Focus Disease Control

- Our proprietary system isolates the liver circulation, delivers a substantially higher concentration of chemotherapy (melphalan) to the liver 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 and perfusionist
- We believe more than 180 treatments with improved device and procedure in US and EU provides confidence safety can be validated in a controlled setting

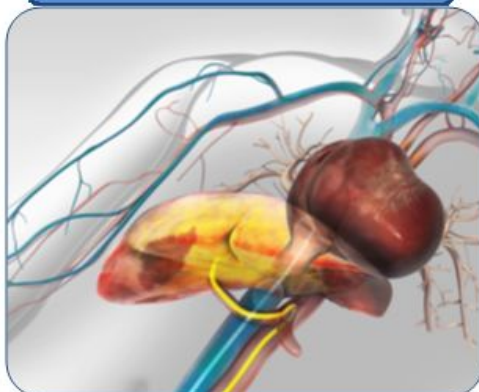
Concentrating the Power of Chemotherapy for Disease Control in the Liver

The Melphalan Hepatic Delivery System (HDS)

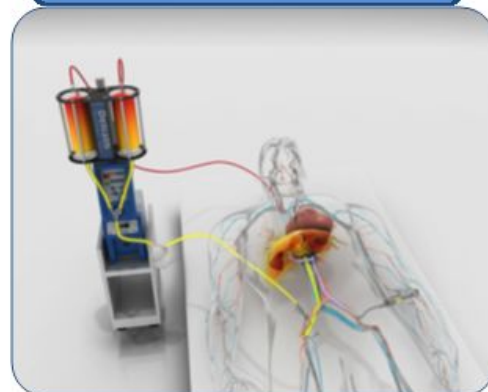
Liver Isolated Via Double Balloon Catheter In IVC



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

More Than 240 Patients Treated To Date

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
Chemosaturation (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

An Established Drug for Liver Cancer Therapy

The Evidence for Melphalan

- Melphalan, an established chemotherapy agent, is proven active at high doses with broad antitumor activity

Authors	Technique	N	Tumor	Drug(s)	ORR, %	Median OS, months
Grover et al. 2004	IHP	13	NET	Melphalan ± TNF	50	48
Noter et al. 2004	IHP	8	Ocular melanoma	Melphalan	50	10
Alexander et al. 2000	IHP	22	Ocular melanoma	Melphalan ± TNF	62	11
Alexander et al. 2003	IHP	29	Ocular melanoma	Melphalan	62	12
Alexander et al. 2009	IHP	120	Colorectal	Melphalan ± TNF, TNF	61	17
van Iersel et al. 2008	IHP	154	Colorectal	Melphalan	50	25
van Iersel et al. 2010	IHP	99	Colorectal	Melphalan	–	25
Verhoef et al. 2008	PHP	24	Various	Melphalan	62	–

1. Grover AC, et al. Surgery 2004;136:1176-82

2. Noter SL, et al. Melanoma Res 2004;14:67-72

3. Alexander HR Jr, et al. Clin Cance Res 2000;6:3062-70

4. Alexander HR Jr, et al. Clin Cance Res 2003;9:6343-9

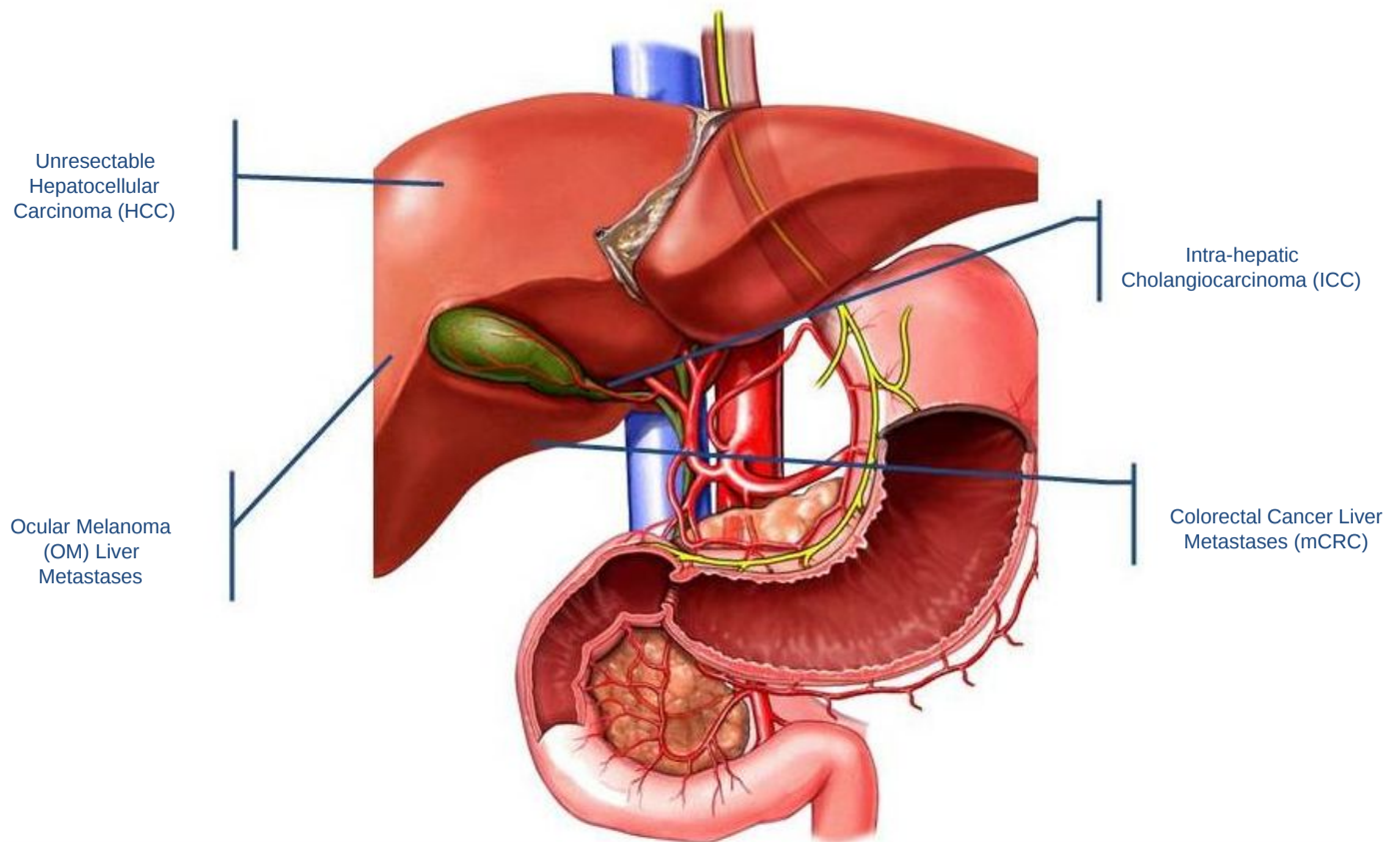
5. Alexander HR Jr, et al. Ann Surg Oncol 2009;16:1852-9

6. Van Iersel LB, et al. Ann Oncol 2008;19:1127-34

7. Van Iersel LB, et al. Ann Oncol 2010;21:1662-7

8. Verhoef C, et al. Ann Surg Oncol 15:1367-74

Potential Applications



Multiple Opportunities Yields Potential Multi-Billion Dollar Global Market

Total Available EU & US Market Opportunity

Cancer Type	Annual Incidence ¹	Eligible Pts ²	Revenue per Patient ³	Annual Potential Market Opportunity (millions)
Ocular Melanoma (OM)	5,700-8,600	2,600-4,300	\$40,000-\$50,000	\$104-\$215
Cholangio Carcinoma (ICC)	11,500	6,500	\$40,000-\$50,000	\$260-\$330
Hepatocellular Carcinoma (HCC)	64,500	7,600-14,700	\$40,000-\$50,000	\$304-\$735
Colorectal (CRC)	411,000	40,000-55,000	\$40,000-\$50,000	\$1,600-\$2,750
Total EU and US	492,700-495,600	56,700-80,500		\$2,268-\$4,030

Notes:

- 1) Source: Globocan, American Cancer Society
- 2) Source: LEK, Booz/PwC, Company estimates
- 3) Assumes an average of two treatments per patient

Effective Liver Cancer Treatment Remains a Major Unmet Medical Need

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 Overview

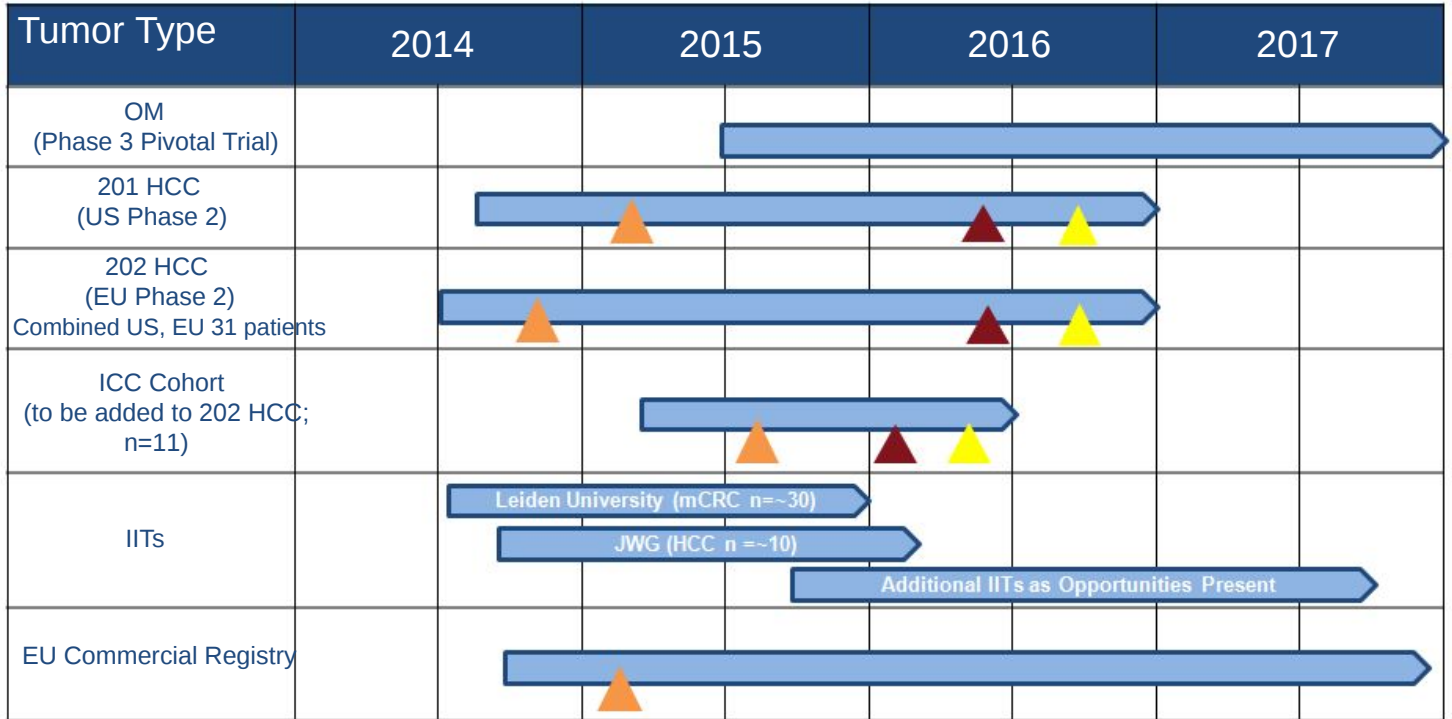
- Initiating global phase 3 trial mid-year in Ocular Melanoma (OM) Liver Mets
- Establish Proof of Concept in Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)
 - Commenced Global Phase 2 Program in HCC in 2014
 - Expanding Program to include ICC Cohort in EU Trial
- Initiating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

Focused on Liver Dominant, Orphan Diseases With High Unmet Need

Clinical Development Program at a Glance

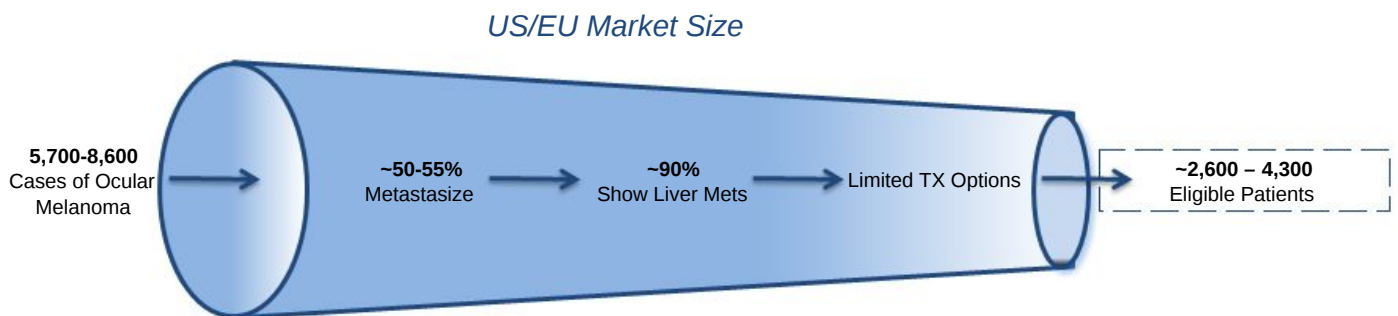
Trials	Tumor	Objectives
Phase 3 Pivotal Trial	OM liver mets	<ul style="list-style-type: none"> ▪ Global Phase 3 trial to start mid 2015 ▪ Primary endpoint: Overall Survival (OS) ▪ Believed to be fastest pathway to NDA approval in the US
Phase 2 Trial	HCC (unresectable confined to the liver)	<ul style="list-style-type: none"> ▪ Protocol 201 (US Only) ▪ Safety, efficacy of Melphalan/HDS treatment <u>followed by sorafenib</u> <ul style="list-style-type: none"> ▪ Evaluate ORR (mRECIST) ▪ Assess safety, PFS ▪ Characterize systemic exposure of melphalan ▪ Assess patient QoL
		<ul style="list-style-type: none"> ▪ Protocol 202 (EU Only) ▪ Safety, efficacy of Melphalan/HDS <u>treatment w/o sorafenib</u> in patients with unresectable liver cancer <ul style="list-style-type: none"> ▪ Evaluate ORR (mRECIST) ▪ Assess safety, PFS ▪ Characterize systemic exposure of melphalan ▪ Assess patient QoL
Phase 2 Cohort	ICC (unresectable confined to the liver)	<ul style="list-style-type: none"> ▪ To be added to Protocol 202 HCC Trial ▪ ORR of Melphalan/HDS treatment in patients with intra-hepatic cholangiocarcinoma (ICC) <ul style="list-style-type: none"> ▪ Other measures as specified in the 202 EU protocol ▪ Signal seeking go/no-go decision by 1H-2016
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"> ▪ Data collection on safety, QoL assessments ▪ Potential efficacy signals in additional tumor types ▪ Support reimbursement in key markets

Clinical Development Program – Timeline



OM Rationale

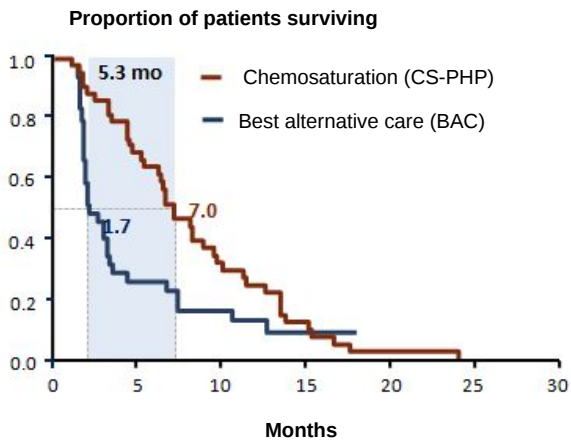
- OM has high incidence of liver metastases
 - Up to 90% of patients with metastases will have liver involvement
 - Life expectancy of approximately 6 months
 - 5,700 - 8,600 cases of OM liver metastases diagnosed in US and EU annually
- Clear efficacy signal seen in prior P3 trial of Melphalan/HDS
- 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



Proven Efficacy in Attractive Orphan Opportunity

Previous Ocular Melanoma Phase 3 Results

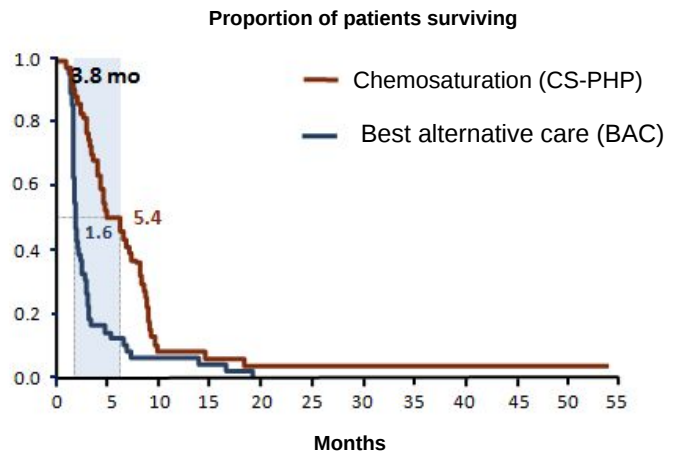
Hepatic Progression Free Survival (hPFS)



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)



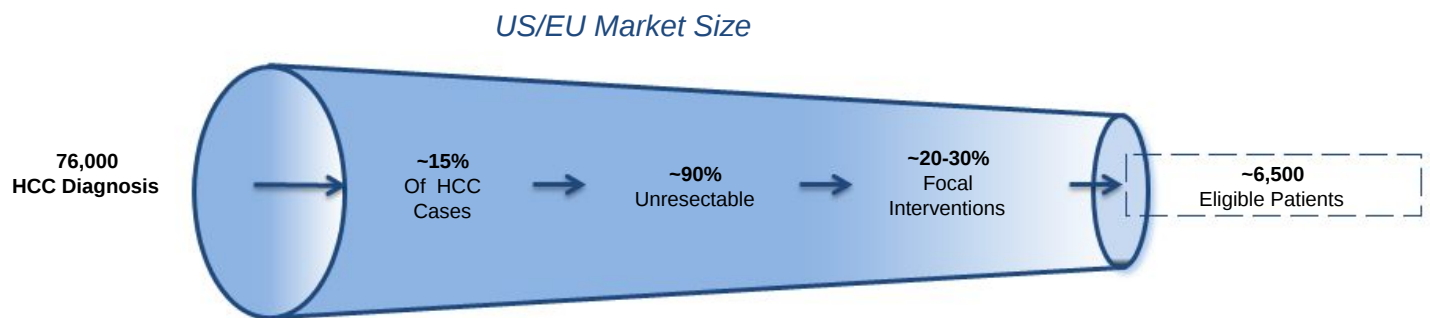
Intent-to-Treat Analysis (June 2012)

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

Clinically Meaningful Benefit Previously Demonstrated for Metastatic OM Patients

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

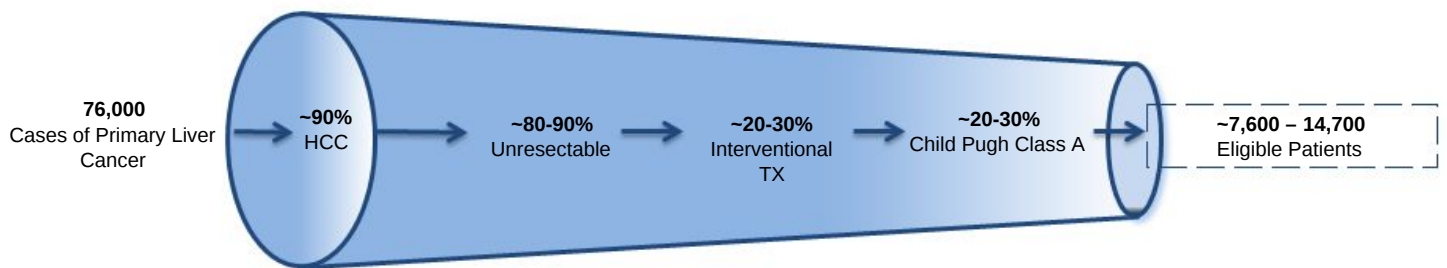


Encouraging Early Commercial Activity in Disease With Limited Treatment Options

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

US/EU Market Size



Large, Deadly Disease in Need of Better Treatments

Prior FDA Experience

- New Drug Application (NDA) submitted August 2012 seeking indication in OM liver metastases with prior filters and procedure
- ODAC meeting in May 2013
 - Negative Vote
 - 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 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
- Deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments

Treating Physicians in US and EU Report Improved Safety Profile

Safety Improvements Implemented

- New generation filter
 - o improved filter efficiency and consistency
- Vasopressors and methylprednisolone
 - o reduce cardiovascular risk
- Prophylactic transfusions and growth factors
 - o reduce risk of myelosuppression
- Intra-arterial nitroglycerin
 - o to prevent hepatic arterial spasm
- Liver tumor burden not to exceed >50%
 - o to address risk of liver failure

Decisive Measures to Seek to Improve Safety Implemented

Positive Developments

- Improved device and procedure since prior trials
 - o >180 treatments with improved device and procedure in US and EU
 - o Many issues raised at ODAC have not been reported
- 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 63% positive response (47% had a partial response and 16% had a complete response)
 - o Moffitt reported 67% positive response (partial response and one complete response)
 - o Leiden reported 80% positive response (partial response)

Patients Report Improved Quality of Life

European Commercialization

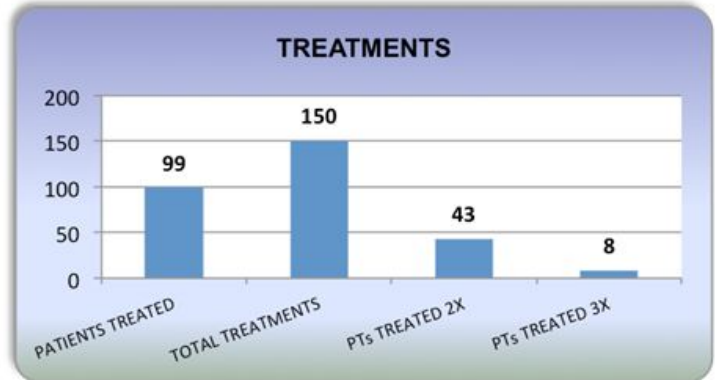
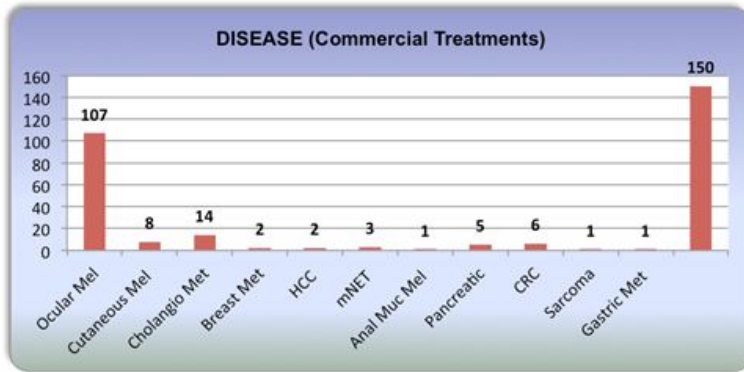


CHEMOSAT® Hepatic Delivery System

- 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
- 150 commercial procedures performed in 15 leading cancer centers in the EU
- Reimbursement via Individual Funding Requests; NUB Value 4 Status in Germany
- UK Block Grants pending & private pay insurance

CHEMOSAT® Commercial Treatments in Europe

- Multiple Tumor Types Treated Since EU Launch



Treatments/Re-treatments Increasing

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 Röntggestr 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

Clinical Evidence and Awareness Continue to Build

Cash & Capital Resources

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

Debt **None**

ATM Program ¹ **\$40 million available at September 30, 2014**

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

1) Subject to market conditions and certain limitations

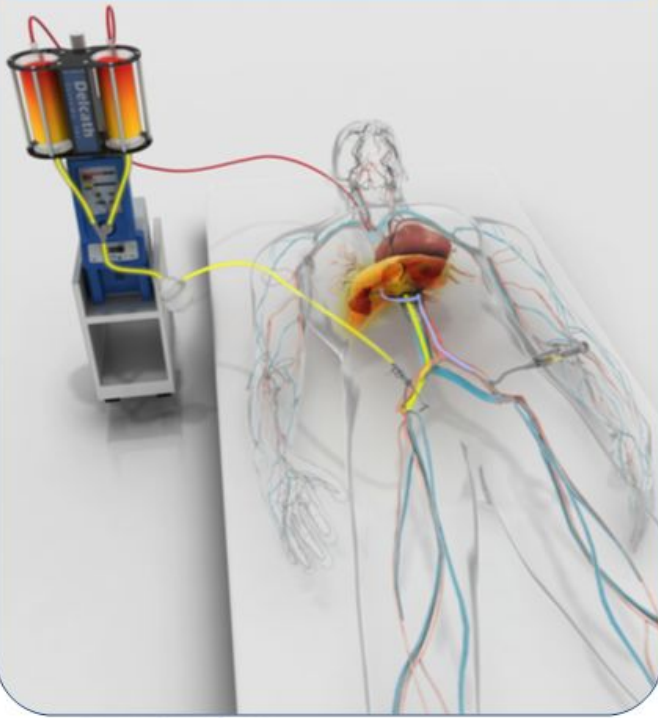
2) Fully diluted includes approximate 0.2 million options and 0.9 million warrants

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

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

Summary

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



- *Cancers of the liver remain a large, multi-billion dollar unmet medical need*
- *Unique, highly differentiated solution*
- *Late-stage asset*
- *Compelling emerging data*
- *Imminent Valuation milestones*
- *Attractive orphan drug business model*
- *Experienced pharmaceutical management team executing a data-driven plan*

Concentrating the Power of Chemotherapy™

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