

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

FORM 8-K

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

Date of report (Date of earliest event reported): **August 14, 2013 (August 13, 2013)**

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)

566 Queensbury Avenue, Queensbury, New York, 12804
(Address of principal executive offices, including zip code)

(518) 743-8892
(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 presented at the Wedbush Pacgrow Life Sciences Management Access Conference on Tuesday, August 13, 2013 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.

Item 9.01. Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

Exhibit No.	Description
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: August 14, 2013

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)

August, 2013

Forward-looking Statements

Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the impact of the negative advisory vote by the ODAC panel on the FDA's decision regarding the Company's new drug application (NDA), timing of completion of the FDA's review of our NDA, the extent to which the FDA may request additional information, data, or new clinical trials and our ability to provide the same in a timely manner, additional extensions to the PDUFA date by the FDA, acceptability of the Phase 1, 2 and 3 clinical trial data by the FDA, FDA approval of the Company's NDA for the treatment of ocular metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with primary and metastatic disease in the liver, our ability to obtain reimbursement for the CHEMOSAT system in various markets, the timing and results of future clinical trials including without limitation the HCC trials, approval of the current or future chemosaturation system for delivery and filtration of melphalan, doxorubicin 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 including Australia and key Asian markets and 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 research, development, clinical trials and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

Investment Rationale

- Clinically proven therapeutic concept for liver cancers
- Positive efficacy signal in multiple tumor types
- Initiating Clinical Development Plan in first line treatment for Hepatocellular Carcinoma (HCC)
 - Yuman Fong, MD (Memorial Sloan-Kettering), world renown expert in primary liver cancer, to act as Study Chair
- Intend to seek strategic partner for Phase 3 HCC trial
- Developing Compelling Reimbursement in Key EU Markets
- Manageable Cash Spend

Focusing Our Business on These Core Objectives

- Pursuit of new clinical trials to support regulatory applications in hepatocellular carcinoma (HCC)
- EU Commercialization of the Hepatic CHEMOSAT® Delivery System, with near term focus on:
 - Expanding clinical usage
 - Obtaining compelling reimbursement in key markets
- U.S. Food & Drug Administration (FDA) approval of New Drug Application (NDA) for Melblez™ Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) (Melblez Kit)

Multiple Capital Resources Available to Execute Plan

Cash & Cash Equivalents: **\$32.3 million at June 30, 2013**

ATM Program **up to \$48.2 million available as of July 31, 2013**

Committed Equity Financing Facility (CEFF) **Up to \$23.9 million as of July 31, 2013**

Working Capital Line of Credit: **\$20 million credit facility**

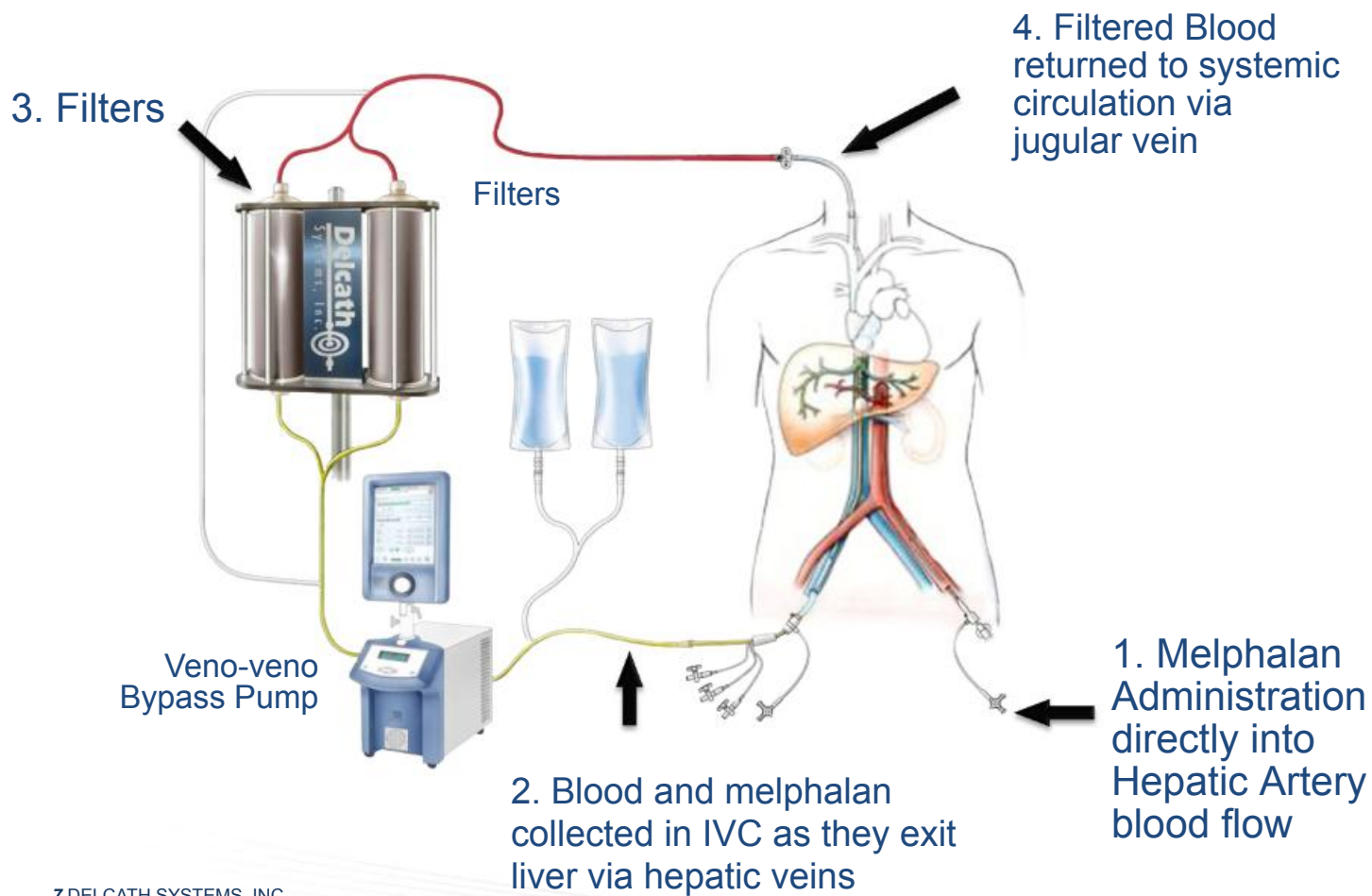
Strategic Partner(s) **Intend to Seek Partner to Finance Phase 3 HCC Trial**

Financial Update

Debt:	None
Cash Utilization:	\$11.3 million in Q1 2013 \$10.5 million in Q2 2013 <u>Projected quarterly cash spend:</u> \$9-\$10 million for Q3 2013 \$6-\$8 million for Q4 2013
Shares Outstanding:	101.6 million (112.0 million fully diluted¹⁾) as of July 31, 2013

1) Fully diluted includes an additional 5.0 million options and 5.4 million warrants

How the Combination Product Works



U.S. Market

Melblez Kit™ (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System)

- Proprietary Drug/Device Combination Product Regulated as a drug 505(b)(2) NDA by U.S. FDA
- Proposed initial indication for the treatment of patients with unresectable ocular melanoma metastatic to the liver
- Melblez Kit comprised of Melblez™ (melphalan hydrochloride for injection) and the Delcath Hepatic Delivery System
- PDUFA Date: September 13, 2013

Ex U.S. Markets

CHEMOSAT® Hepatic Delivery System

- Regulated as a Class IIb Medical Device
- Indicated for the intra-hepatic of administration of melphalan hydrochloride and subsequent filtration of the venous blood return.
- CHEMOSAT Kit supplied without melphalan

U.S. Status

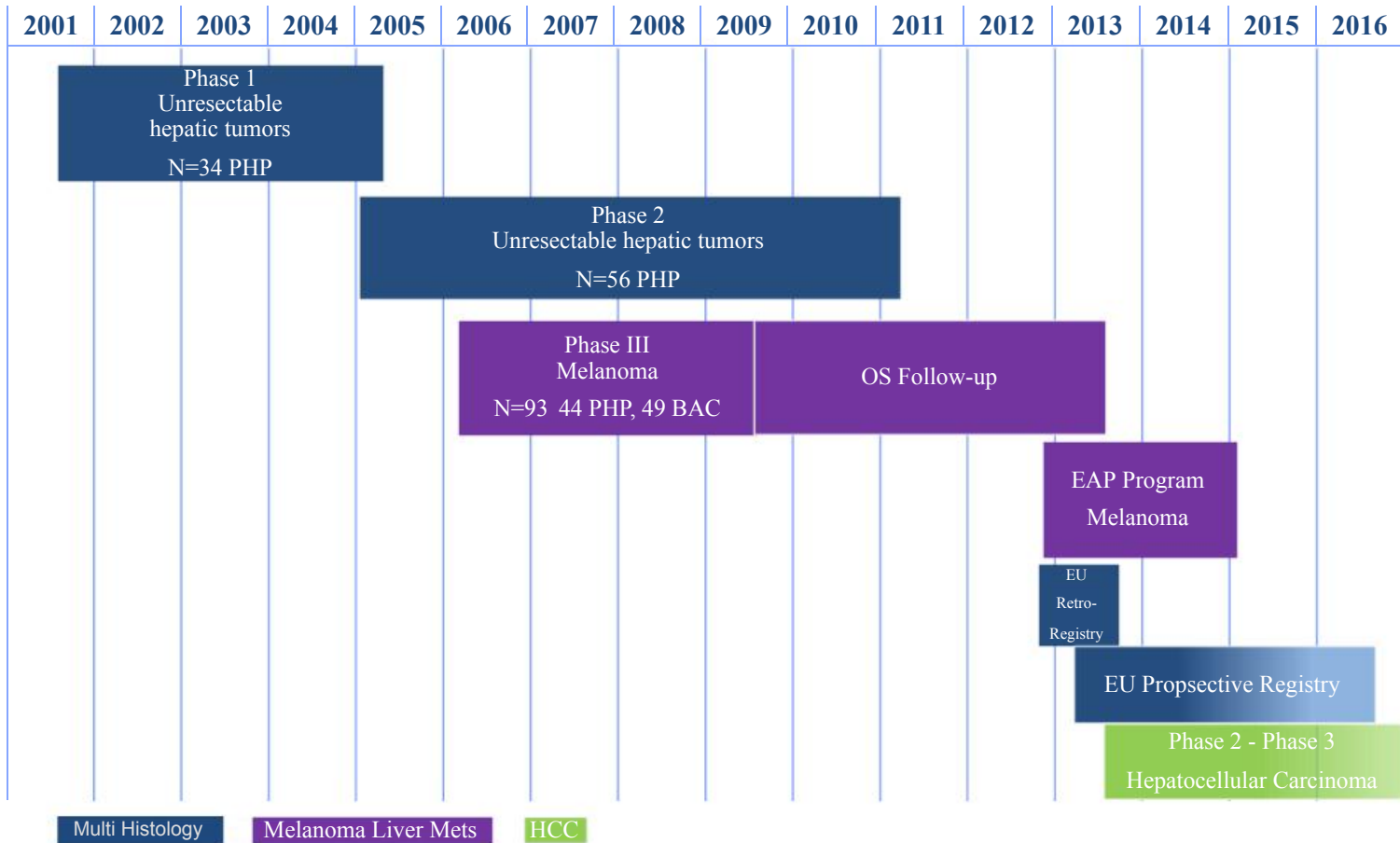
- New Drug Application Pending
 - Oncology Drug Advisory Committee (ODAC) negative vote based on procedural safety concerns that Company believes were corrected via protocol amendments and related procedure refinements
 - Investigator reported deaths seen on trial did not occur again following protocol amendments (in the opinion of the treating investigators)
 - Gen 2 filter contained in the Chemistry, Manufacturing and Control (CMC) module as a technical change - Company believes use of Gen 2 coupled with procedure refinements offer improved patient experience via shorter hospital stays and reduced impact to blood components as observed in EU, EAP and Compassionate Use experience
 - Actively collecting Gen 2 clinical data
 - § U.S. Expanded Access Program (melanoma)
 - § EU retrospective & prospective registries (mixed histologies)

FDA Action Expected in September

Risks associated with the CHEMOSAT/Melbez Kit Procedure

- In clinical trials, the integrated safety population of patients showed risks associated with the CHEMOSAT/MELBLEZ Kit procedure to include:
 - a 4.1% incidence of deaths due to adverse reactions;
 - 4% incidence of stroke;
 - 2% reported incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment;
 - a $\geq 70\%$ incidence of grade 4 bone marrow suppression with a median time of recovery of greater than 1 week;
 - and an 18% incidence of febrile neutropenia, along with the additive risk of hepatic injury, severe hemorrhage, and gastrointestinal perforation.
 - See Appendix for details
- Deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments.
- The trials that comprised this integrated safety population used early versions of the CHEMOSAT/Melbez Kit system, including the Generation One filter, and did not include use of the Generation Two filter.
- Death rate comparable to approved labeling for IV Melphalan
- While cancer treatments have certain inherent risks, the Company believes that the risks associated with this procedure are manageable

Clinical Development Positive Efficacy Signals in Multiple Liver Tumor Types



HCC Rationale - US & Global

- Large Global Market
 - HCC most common primary cancer of the liver
 - ~750,000* new cases diagnosed worldwide annually
 - ~100,00 potentially suitable for treatment with Melblez/CHEMOSAT
- Liver centric disease, liver centric treatment
- Large unmet need in first line therapy
 - Only one currently approved chemotherapy in U.S., Europe, certain Asian markets
 - Only 10-20% of patients are candidates for surgical resection
 - Focal interventions
 - § Considering micro-metastases, cannot treat entire liver
 - § Limited clinical data

- Best hepatic tumor response by RECIST assessed by investigators
 - Partial response (PR) 1 patient (12.2 mos, survived 20.47 mos)
 - Stable disease (SD) 3 patients (PFS 3.45-815 mos, survival 5.26-19.88 mos)
 - Not assessed or evaluable 1 patients
- No evidence of extrahepatic disease progression

*Source: GLOBOCAN

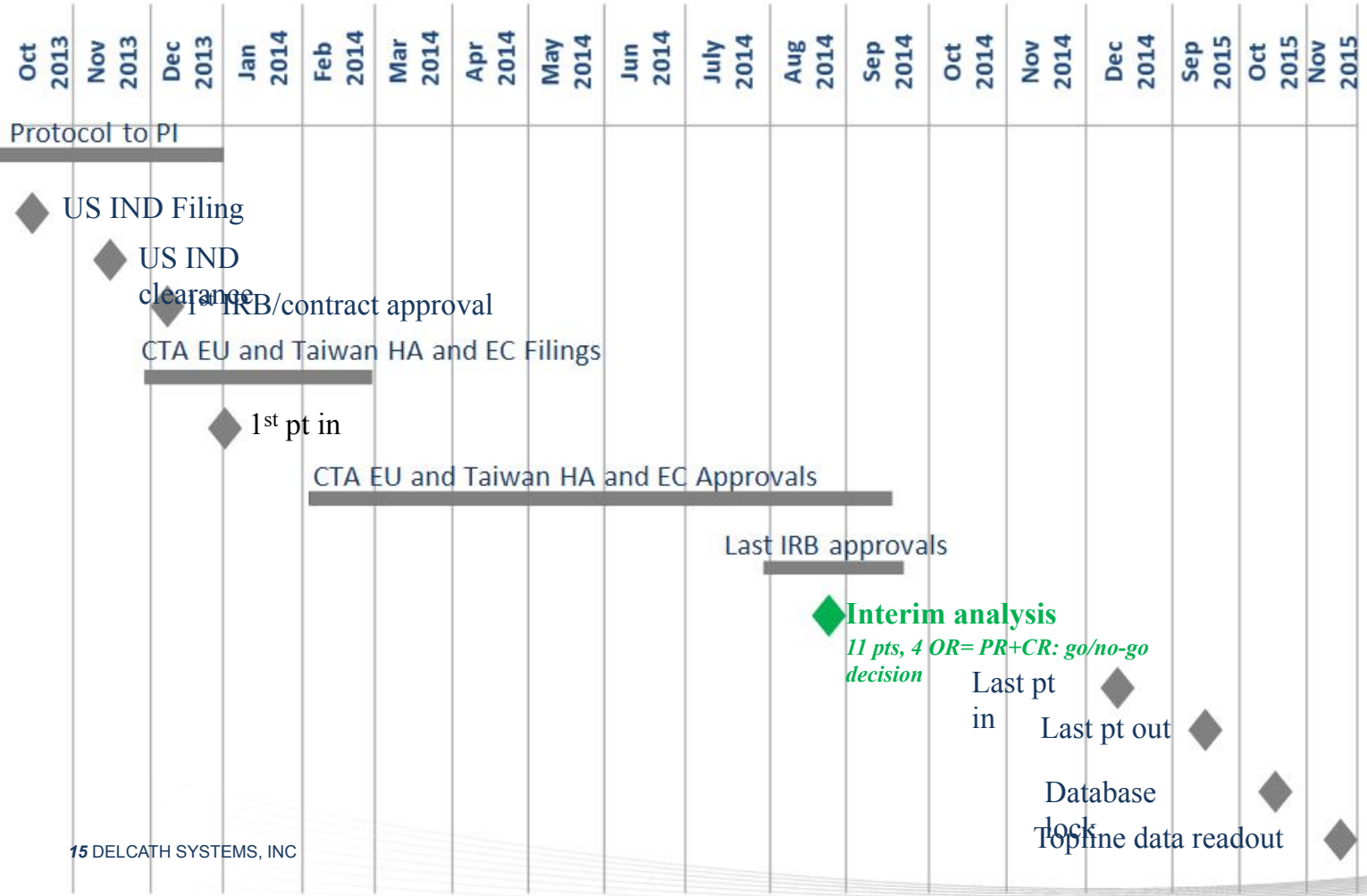
Encouraging Positive Signal for Primary Liver Cancer

Staged Hepatocellular Carcinoma (HCC) Trial Plan

- Global Phase 2 - first line treatment for unresectable, advanced HCC confined to the liver
 - § Yuman Fong, MD, (Memorial Sloan-Kettering) - Study Chairman
 - § Multi-center, open label trial
 - § Early opportunity for interim analysis/proof of concept in 2014
 - § Intend to seek partners on strength of interim Phase 2 analysis
 - § Plan to include Taiwan partner (Chi Fu)
- Global Phase 3 - first line
 - § Intend to initiate following Phase 2 assuming positive results
 - § Planning for Phase 3 concurrently with Phase 2

Initiating HCC Plan End 2013, Subject to FDA Agreement

Clinical and Regulatory HCC Phase 2 - Anticipated Milestones



Additional Clinical Data Generation

- FDA has accepted IND Amendment that includes Gen 2 device in US Expanded Access Program (EAP), compassionate use (CU), and all future clinical trials
- US EAP with Gen 2 initiated in January 2013; two patients received a total of 5 treatments
- Activating EU Registries to systematically collect Gen 2 data from commercial experience
 - Retro-data collection underway at 7 EU hospitals
 - Initiating Prospective Registry in Q3
- Supporting investigator-initiated trials (IITs) globally in multiple tumor types

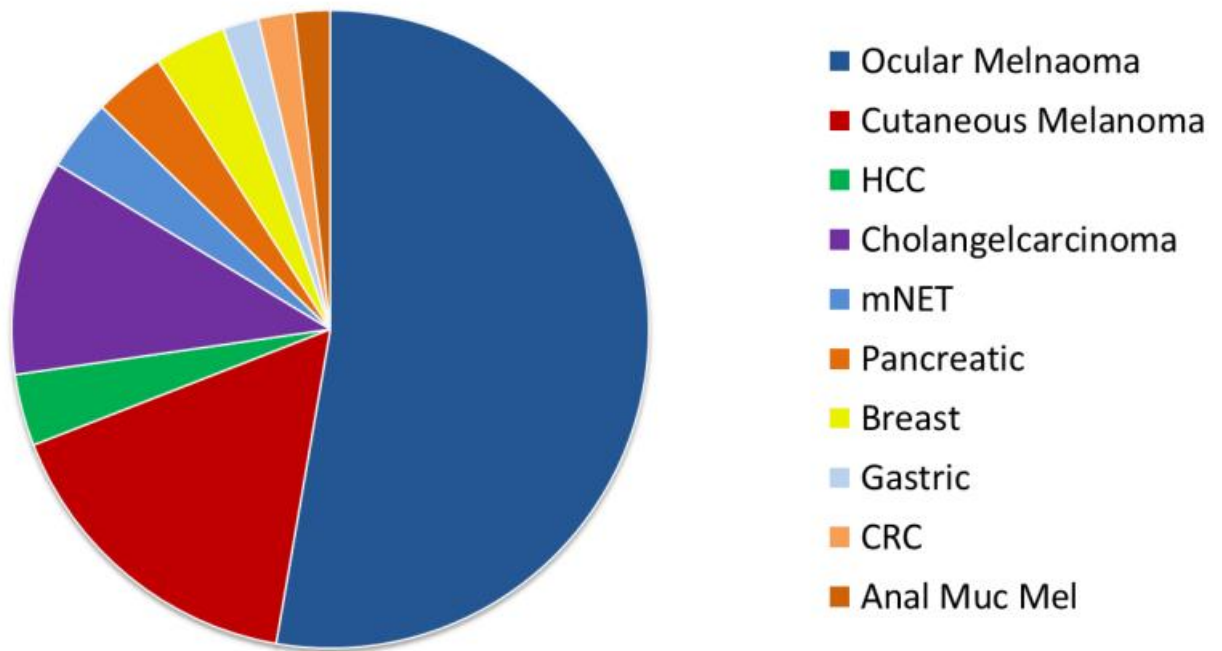
Establish PHP/Melphalan as Standard of Care (SOC) for Disease Control in the Liver

CHEMOSAT: Expanding Clinical Use in the EU

- Continued pre-commercial activities in key EU countries -
 - Current focus on Germany, UK, Italy
 - Secondary focus on Netherlands, Spain, Ireland, France
- 12 EU Clinical Sites as of August 2013
- EU clinicians using CHEMOSAT for a broad range of liver metastases
 - Use includes: cutaneous melanoma, ocular melanoma, colorectal cancer (CRC), gastric cancer, breast cancer, neuroendocrine tumor (NET), hepatocellular carcinoma (HCC) and cholangiocarcinoma

Expanding EU Clinical Adoption

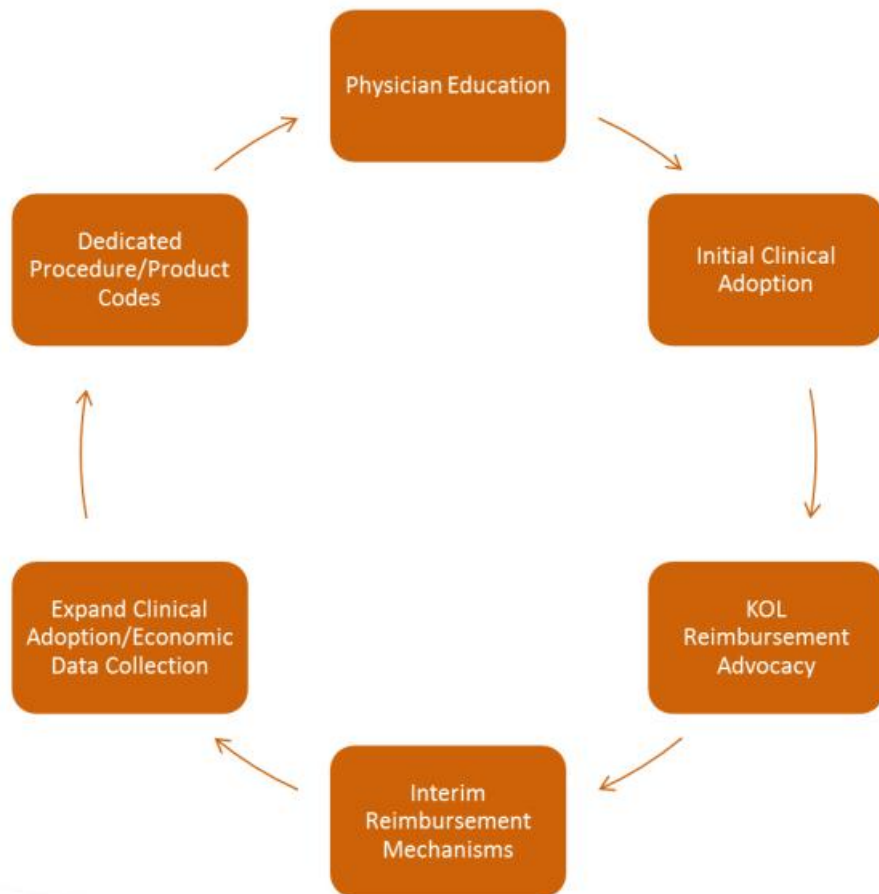
CHEMOSAT: Multiple Tumor Types Treated in Europe



CHEMOSAT Centers in Europe

- **Milan, Italy - European Institute of Oncology**
- **Frankfurt, Germany - Johann Wolfgang Goethe-Universität**
- **Villejuif, France - Cancer Institute Gustave Roussy**
- **Bordeaux, France - Hôpital Saint-André**
- **Galway, Ireland - University Hospital Galway**
- **Southampton, United Kingdom - Southampton University Hospital**
- **Göttingen, Germany - University Medical Center Göttingen**
- **Varese, Italy - Varese University Hospital**
- **Amsterdam, The Netherlands - Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital**
- **Heidelberg, Germany - University of Heidelberg Hospital**
- **Berlin, Germany - Berlin Charité Hospital**
- **Palma, Spain - Majorca Hospital**

Driving Compelling Reimbursement



EU REIMBURSEMENT STATUS

2012

2013

2014

2015



ZE Application
(German Radiology Society)

ZE Denied
NUB
Submission
10/2012

NUB Value 4 Granted
2/2013
ZE Resubmission
March 2013

NUB Resubmission
September 2013

NUB Decision
1 Feb 2014

DRG Code
2-year data collection
from 1st introduction



Alternative HRG coding
to cover part of procedure

Interim Funding Submission
· Individual funding
· National Cancer Fund
· National Care Commissioner

Interim Funding Decision
10-11, 2013

Block funding
· Application to fund 90 patients
· Decision 10/2013
· Following approval block funds available 4/2014

DRG Code
~2 years after
Phase 3 publication



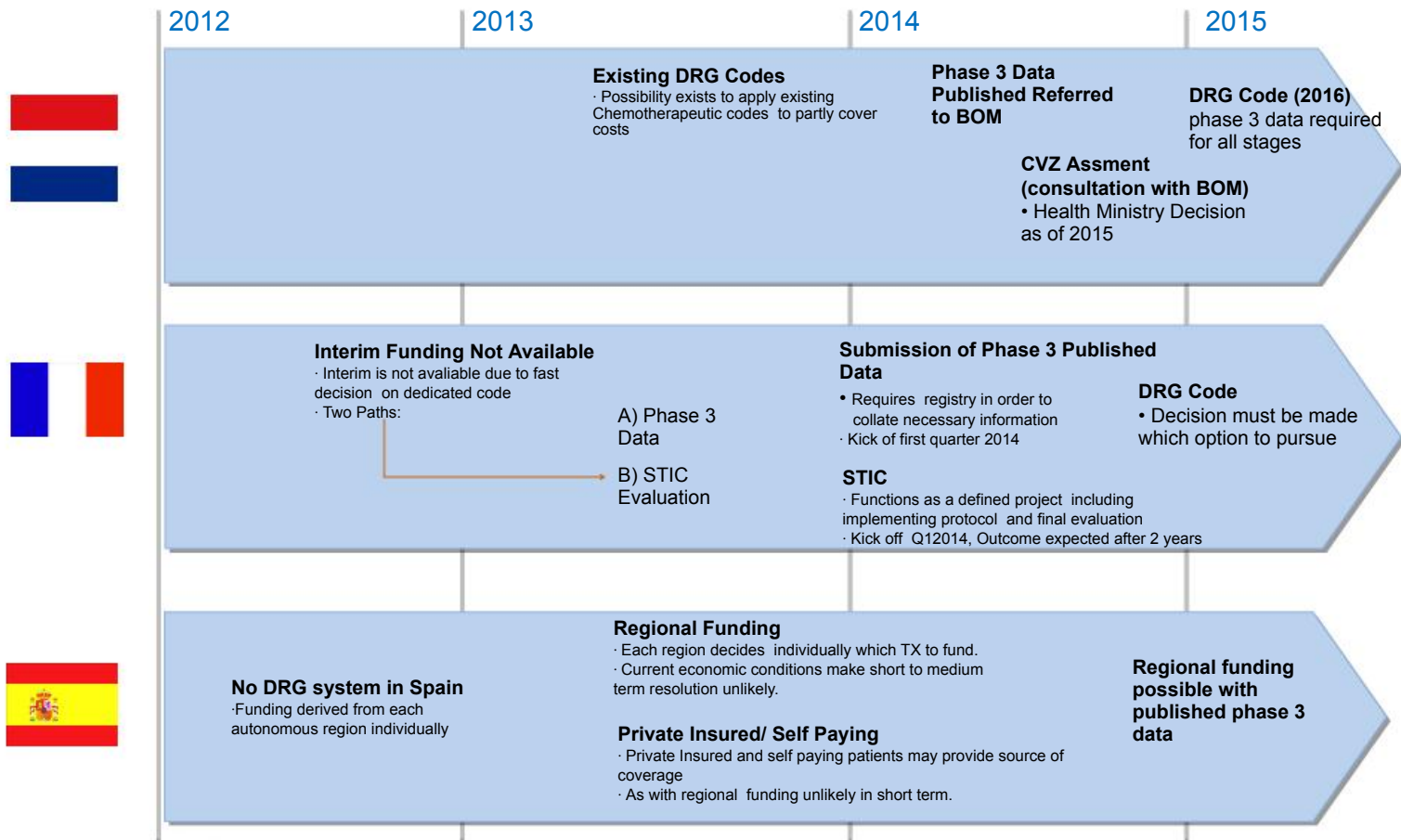
Existing DRG code utilized by Hospital Administration
· Covers 50% of procedure cost

Top-Up Payment Submitted
· Regional supplemental payment
· Hospitals close gaps

Regional Government decision on top up payments
· (Lombardy obtained approval)

DRG Code
~2 years after
Phase 3 publication

EU REIMBURSEMENT STATUS



Publications: Abstracts Accepted in 2012

• Over 20 Abstracts Accepted and Presented in 2012

- Ø Moeslein F. *Chemosaturation therapy - evolution, clinical experience and applications.*
- Ø Deneve JL. *Percutaneous hepatic perfusion for unresectable metastatic sarcoma to the liver.*
- Ø Wood B. *Isolated liver perfusion.*
- Ø Zager J. *Chemosaturation therapy with percutaneous hepatic perfusions of melphalan versus standard of care in patients with hepatic metastases from melanoma: A randomized multicenter phase 3 study.*
- Ø Ferrucci P. *Chemosaturation therapy as part of patient management: an oncologist's perspective.*
- Ø Orsi F. *First European center experience with chemosaturation: an IR's perspective.*
- Ø Vogl TJ. *Chemosaturation therapy: an Interventional Radiologist's perspective on where it fits now and in the future.*
- Ø Ferrucci P. *Chemosaturation therapy with percutaneous hepatic perfusion (CS-PHP) for unresectable hepatic metastases: the European Institute of Oncology (EIO) Experience.*
- Ø Moeslein F. *Chemosaturation with percutaneous hepatic perfusions: vasopressor, nitroglycerin, and pre-embolization requirements*
- Ø Moeslein F. *Chemosaturation with percutaneous hepatic perfusions (CS-PHP): Utilization of vasopressors, nitroglycerin, and pre-embolization*
- Ø Moeslein F. *Chemosaturation using percutaneous hepatic perfusion: pre-embolization of GI branches in a phase 3 clinical trial.*
- Ø Alexander HR. *Percutaneous hepatic perfusion (PHP or CHEMOSAT®) with melphalan versus best alternative care in patients with hepatic metastases from melanoma: A post-hoc analysis of PHP-randomized vs Best Alternative Care (BAC).*
- Ø Gardner ER. *Pharmacokinetic Analysis of Percutaneous Hepatic Perfusion (PHP) of melphalan in patients with hepatic metastases from melanoma.*
- Ø Alexander HR. *Hepatic perfusion (CHEMOSAT® or CS-PHP) of melphalan vs. best alternative care in patients with hepatic metastases from melanoma: Update of a randomized phase 3 trial.*
- Ø Gardner ER. *Percutaneous hepatic perfusion (CHEMOSAT® or CS-PHP) of melphalan in patients with hepatic metastases from melanoma: Phase III results.*
- Ø Ferrucci P. *Chemosaturation therapy with percutaneous hepatic perfusion (CS-PHP) for unresectable hepatic metastases: the European Institute of Oncology (EIO) Experience*
- Ø Gardner ER. *Pharmacokinetic Analysis of Percutaneous Hepatic Perfusion of Melphalan in Patients with Hepatic Metastases from Melanoma*
- Ø Orsi F. *Role of regional therapies compared with advances in systemic treatment for melanoma*

- Abstracts presented in Q1 2013

- Forster M. *Percutaneous hepatic perfusion for unresectable melanoma or sarcoma to the liver: a single institution experience.*
- Testori A. *Chemosaturation therapy with percutaneous hepatic perfusion for unresectable liver metastases: the European Institute of Oncology (EIO) experience.*

- Other accepted abstracts to be presented

- Ferrucci P. *Chemosaturation with percutaneous hepatic perfusions (CS-PHP) of melphalan for hepatic metastases: a comparison between old and new-generation high-efficiency filters. CIRSE 2013*

2013 Planned Publications

- Agarwala, et al. *“Treatment of Melanoma Liver Metastases: Impact on Overall Survival”* Under Review
- Ferrucci, et al. *“Experience with Generation 1 Filters vs Generation 2 Filters”* Under Review
- Alexander, et al. *“Review of Percutaneous Hepatic Perfusion for Ocular Melanoma Liver Metastases”* final stages of review, to be published in American Oncology and Hematology
- Zager, J. *“Moffitt Cancer Center Experience with PHP”*, accepted to the *Journal of Surgical Oncology*, planned early 2014 full publication
- Chen, M. et al. *“Anesthetic Management of Patients Undergoing Percutaneous Hepatic Perfusion of Melphalan for Treatment of Metastatic Liver Cancer”*, final stages of review, hopeful fall 2013 publication
- *Phase III and Phase II Publications - authors report plan to submit by end September, 2013*

Conclusion

- Clinically proven therapeutic concept for liver cancers
- Positive efficacy signal in multiple tumor types
- Initiating Clinical Development Plan in first line treatment for Hepatocellular Carcinoma (HCC)
- Developing compelling reimbursement in Key EU Markets
- Multiple Capital Resources Available
- Intend to seek strategic partner for Phase 3 HCC trial
- Manageable Cash Spend

Concentrating the Power of Chemotherapy™

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APPENDIX

28 DELCATH SYSTEMS, INC

Procedure-related deaths

- Five deaths (4.1%) in the Phase 2 and Phase 3 clinical trials were considered treatment-related and resulted from adverse events
 - Four deaths in Phase 3 trial; one in Phase 2 trial
 - Treatment-related deaths in the pooled percutaneous hepatic perfusion (PHP) population were a consequence of either the PHP procedure; or the direct local effects of melphalan during the procedure, or both
- Two deaths due to gastric ulceration/perforation:
 - A death due to upper GI hemorrhage in the Phase 2 trial in male patient with pancreatic neuroendocrine tumor (NET) who had a prior surgical (Whipple's) procedure and consequent abnormal architecture of the upper GI tract, its vasculature, and biliary tree. Patient died on Day 74 after melphalan/PHP treatment and an autopsy revealed a ruptured right hepatic artery as the primary cause of death.
 - A death due to gastric perforation in a male patient in the Phase 3 trial who crossed over to melphalan/PHP treatment after hepatic progression on best alternative care (BAC). Patient went into cardiopulmonary arrest and died during a laparotomy on Day 18 after his second treatment cycle.

- One death due to hepatic failure:
 - A death due to hepatic failure occurred in male patient in the Phase 3 trial during the first cycle of melphalan/PHP treatment. Following melphalan/PHP treatment, this patient experienced fluid overload, myelosuppression, and hepatorenal syndrome.
 - § An autopsy revealed that this patient's death was related to underlying disease burden as the tumor burden in his liver was greater than 90%.

Two deaths were attributable to complications of neutropenia, beyond the first cycle of treatment

- One patient died of streptococcal sepsis and another died of neutropenic complications.
 - Prophylactic growth factor support, which is used to treat neutropenia, was not protocol specified and rarely used.
 - In patients who have been treated with the Generation Two system, both commercially in Europe and in the US under the Expanded Access Program and compassionate use, we have not seen complicated neutropenia to date.
 - Myelosuppression is always a risk with chemotherapy, Delcath has recommended following the American Society of Clinical Oncology (ASCO) guidelines for the use of growth factors to mitigate the incidence of complicated neutropenia.

ODAC Summary

In FDA's presentation at ODAC, FDA disagreed with this adjudication and added three additional deaths, for a total of a 7% percent death rate, in the Phase 2 and Phase 3 programs.

- Two deaths related to hepatic failure and one death related to myelosuppression, were described.
 - Upon being advised of the FDA's assessment of these deaths, the Company requested that the cases be re-reviewed by the treating principal investigators.
 - After this review, the treating principal investigators continue to be convinced that these patients died of disease progression, and the Company believes that the three additional deaths the FDA attributed to the procedure were unrelated to treatment.

REIMBURSEMENT PLAN - Acronym Definition

Germany

ZE - "Zusatzentgelt" form of additional compensation for approved treatments which are not sufficiently compensated by the existing DRG codes in place.

NUB - "Neue Untersuchungs- und Behandlungsmethoden" provides reimbursement between the gap of availability of new procedures and correct coding in the DRG system.

InEK - "Institut für das Entgeltsystem im Krankenhaus" Institute for the German hospital remuneration system.

Calculation Hospitals - hospitals which collect and submit procedure costs to InEK

UK

HRG - "Health Resource Group" used by the National Health System as a unified set of codes grouping patient events which incur a similar amount of resources. Used by the "Payment by Result" system to obtain reimbursement for concluded patient episodes/treatments.

NICE - "National Institute for Clinical Excellence" body which reviews and publishes guidance on new treatment methods. Guidance is internationally highly recognised.

Netherlands

BOM - "Beoordeling Oncologische middelen" assessment board for oncological treatment.

CVZ - "College voor Zorgverzekeringen" Dutch Healthcare Insurance Board.

France

STIC - "Soutien aux techniques innovantes coûteuses" fund set aside for innovative devices especially for the treatment of cancer.

Other

DRG - "Diagnosis Related Group" coding system classifying patient treatments and used to obtain reimbursement for procedures carried out (same as HRG for UK)