

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): **October 17, 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))
-

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.

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: October 17, 2013

By: /s/ Barbra C. Keck
Name: Barbra C. Keck
Title: Vice President, Controller & Principal Accounting Officer

EXHIBIT INDEX

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



Investor Presentation

(NASDAQ: DCTH)

October 2013

Forward-looking Statements

This presentation contains forward-looking statements, within the meaning of federal securities laws, related to future events and future financial performance which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements that are not historical facts. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including, but not limited to, uncertainties relating to: efficiencies and reduction in cash utilization achieved through September 2013 staff reductions, the leadership transition plan and its impact on the Company, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter and provide the same in a timely manner, 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 overall economic conditions and other factors described in our filings with the Securities and Exchange Commission including the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K and our Reports on Form 10-Q and Form 8-K.

Investment Thesis

- § Liver cancer therapy company
- § Innovative Delcath Hepatic Delivery System (HDS) in combination with high dose well-established chemotherapeutic drug Melphalan to address an underserved liver cancer market
- § Clinically proven therapeutic concept for liver cancers
- § Positive efficacy signal in multiple tumor types
- § Seeking compelling reimbursement in key EU markets
- § Intend to initiate Phase 2 clinical development program in patients with unresectable Hepatocellular Carcinoma (HCC)
- § Manageable cash spend to support core objectives

Ex U.S. Markets

CHEMOSAT® Hepatic Delivery System

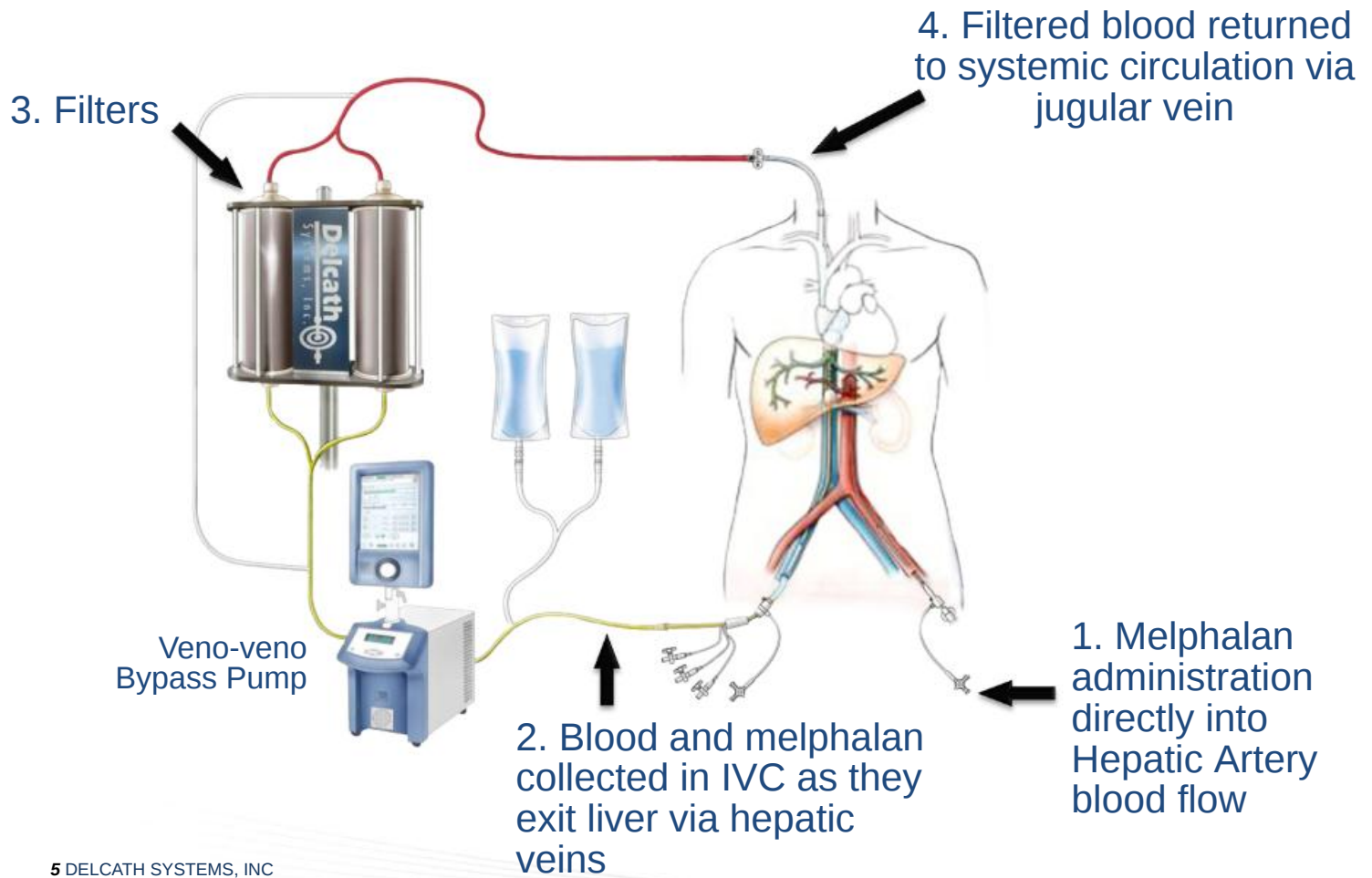
- § Regulated as a Class IIb Medical **Device**
- § Indicated for the intra-hepatic of administration of melphalan hydrochloride and subsequent filtration of the venous blood return
- § CHEMOSAT Kit supplied without melphalan
- § In EU, the product at market access and clinical adoption stage
- § Seeking reimbursements: NUB-1 in Germany, block grant in UK

U.S. Market

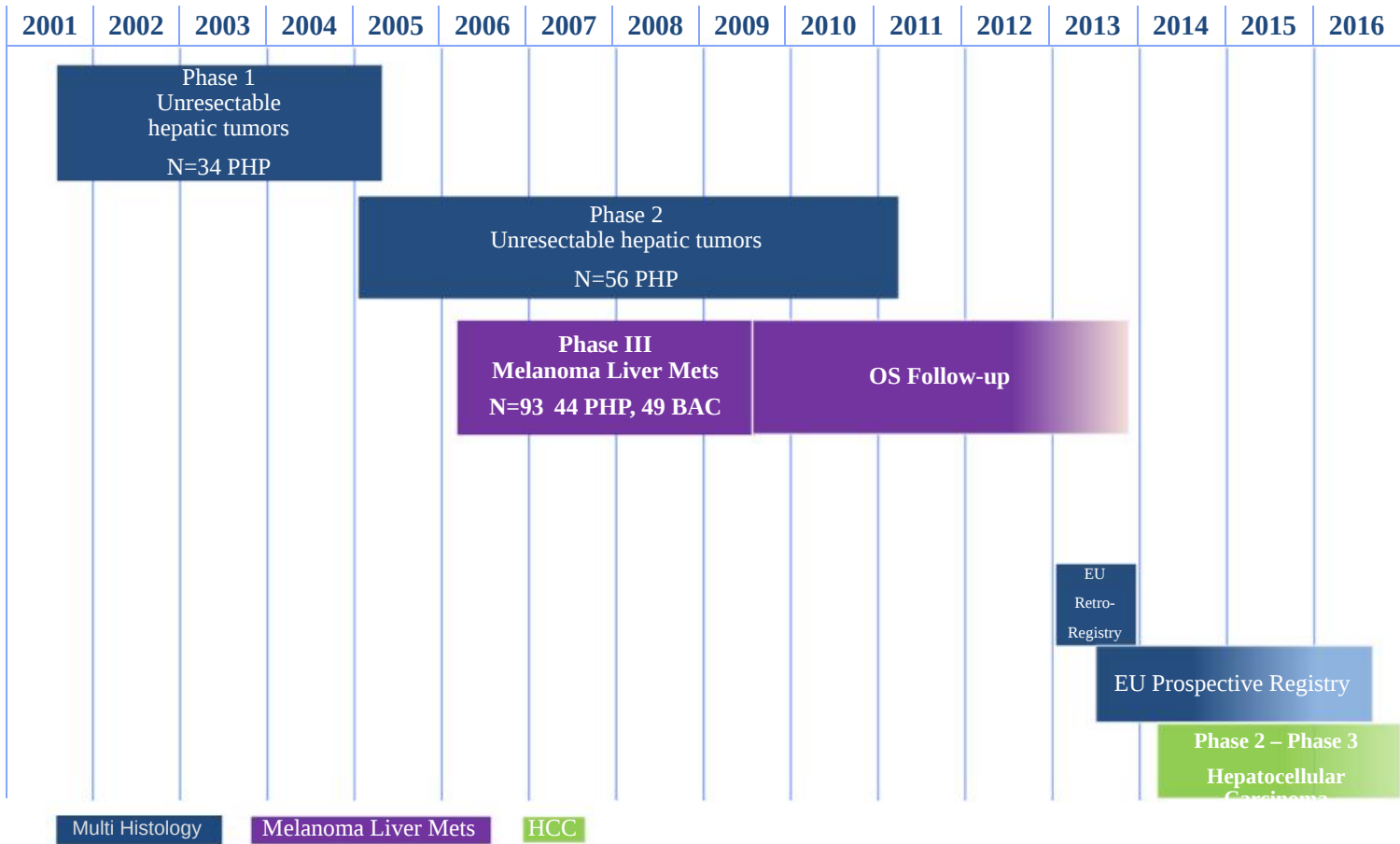
Melphalan for Injection with Delcath Hepatic Delivery System

- § Clinical development stage - proprietary **Drug/Device Combination Product**
Regulated as a drug 505(b)(2) NDA by the FDA
- § FDA Complete Response Letter (CRL) in September, 2013 to NDA for indication of unresectable ocular melanoma liver metastasis
- § Type A meeting requested to seek guidance on additional requirements for OcuMel program
- § Intend to conduct global HCC clinical program

The Delcath Hepatic Delivery System



Positive Efficacy Signals in Multiple Liver Tumor Types

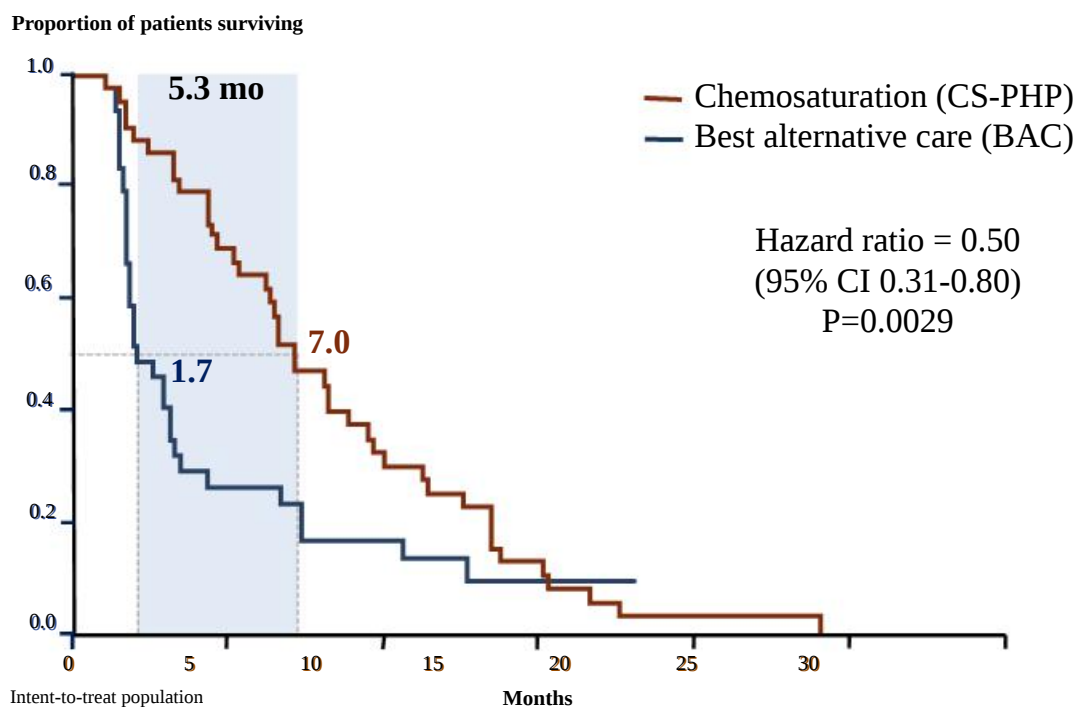


Clinically Differentiated Results

- § Phase 1, 2 and 3 trials produced positive results in multiple tumor types
- § 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 Intent to Treat (ITT) basis
- § Hepatocellular Carcinoma (HCC)
 - § Encouraging signal in HCC cohort of Phase 2 trial
- § 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 months
- § Safety profiles consistent with pivotal US Phase 3 melanoma trial

Phase 3 Results – Primary Endpoint hPFS

Hepatic progression-free survival (IRC)

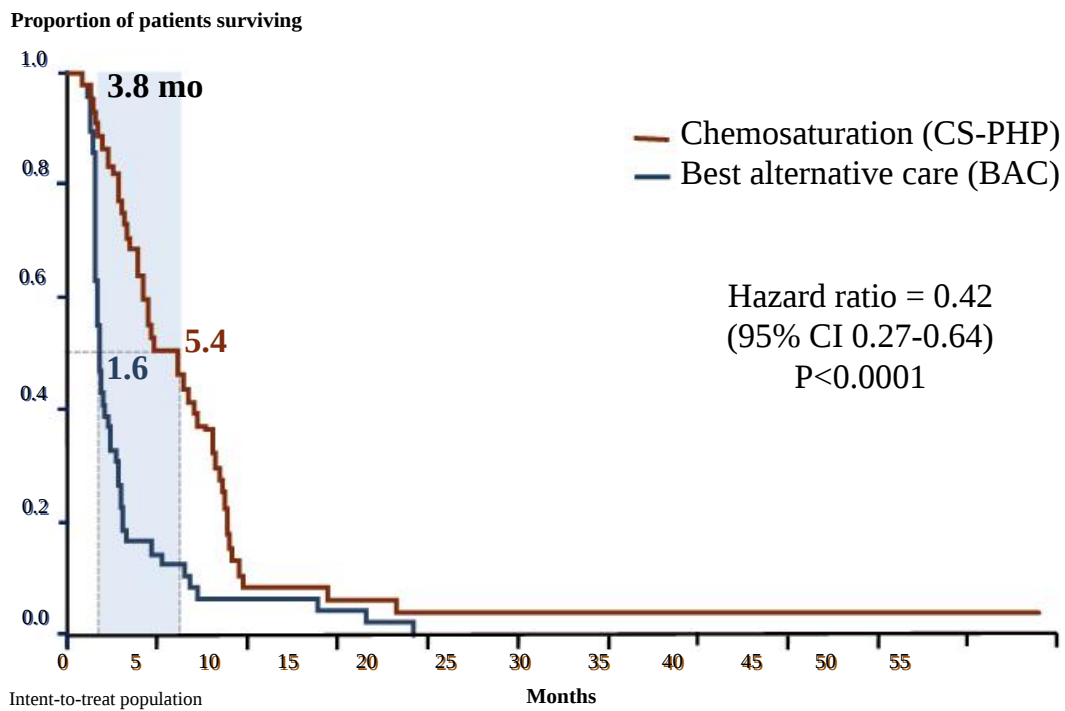


INDEPENDENT REVIEW COMMITTEE (IRC) ASSESSMENT - UPDATED ANALYSIS (4 June 2012)

CS-PHP Demonstrated 4x or 5.3 months Improvement in Primary Endpoint of hPFS

Phase 3 Results – Overall PFS

Overall progression-free survival (investigator)



INVESTIGATOR ASSESSMENT - UPDATED ANALYSIS (4 June 2012)

CS-PHP also Demonstrated a Highly Statistically Significant Improvement in Overall PFS

Risks associated with the CHEMOSAT/MELPHALAN HDS Procedure

- § In clinical trials using early versions of the device, the integrated safety population of patients showed risks associated with the MELPHALAN HDS procedure:
 - § 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;
 - § 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
- § Future clinical trials will include use of the Generation Two filter and procedure refinements to better control toxicities

FDA Complete Response Letter (CRL) on Melanoma NDA

- § Issued in September, 2013
- § Among FDA requests
- § 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 its risks
- § Company evaluating the other requirements contained in the letter, and will review potential regulatory paths forward with the FDA.
- § Type A Meeting Requested

**Ocular Melanoma Liver Metastases Program pending
outcome of further discussion with the FDA**

HCC Rationale – U.S. & Global

- Large Global Market
 - HCC most common primary cancer of the liver
 - ~750,000* new cases diagnosed worldwide annually
 - ~100,000 potentially suitable for treatment with CHEMOSAT/Melphalan HDS
- 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
 - 80-90% of patients are not suitable for surgical resection
 - Focal interventions
 - Cannot treat entire liver due to micro-metastases
 - Limited clinical data

*Source: GLOBOCAN

Encouraging Signal in Previous P2 HCC Study with Mel/HDS

Subject ID	Age (yr)	Sex (M/F)	Race	Baseline tumor burden (% of hepatic involvement)	Number of PHP received	Hepatic response/overall response	hPFS (month)	Overall PFS (month)	OS (Month)
008	57	F	white	5	3	SD/SD	4.37	4.37	19.88
010	63	M	white	40	1	NE/NE	3.35d	3.35d	3.35
011	61	M	white	20	4	SD/SD	8.15	8.15	10.12
025	61	M	black	65	3	SD/SD	3.45	3.45	5.26
034	49	M	white	40	4	PR/PR	12.22	12.22	20.47

Global Hepatocellular Carcinoma (HCC) Clinical Plan

- § Global Phase 2 – Mel/HDS – sorafenib sequential treatment of HCC confined to the liver
 - § Multi-center, open label trial
 - § Staged trial design with early opportunity for interim analysis/proof of concept in 2014
 - § Objective Response Rate (CR + PR) after 2 cycles Mel/HDS
 - § Intend to seek partners on strength of interim Phase 2 analysis
- § Global Phase 3 - first line HCC
 - § Intend to conduct following Phase 2 assuming positive results

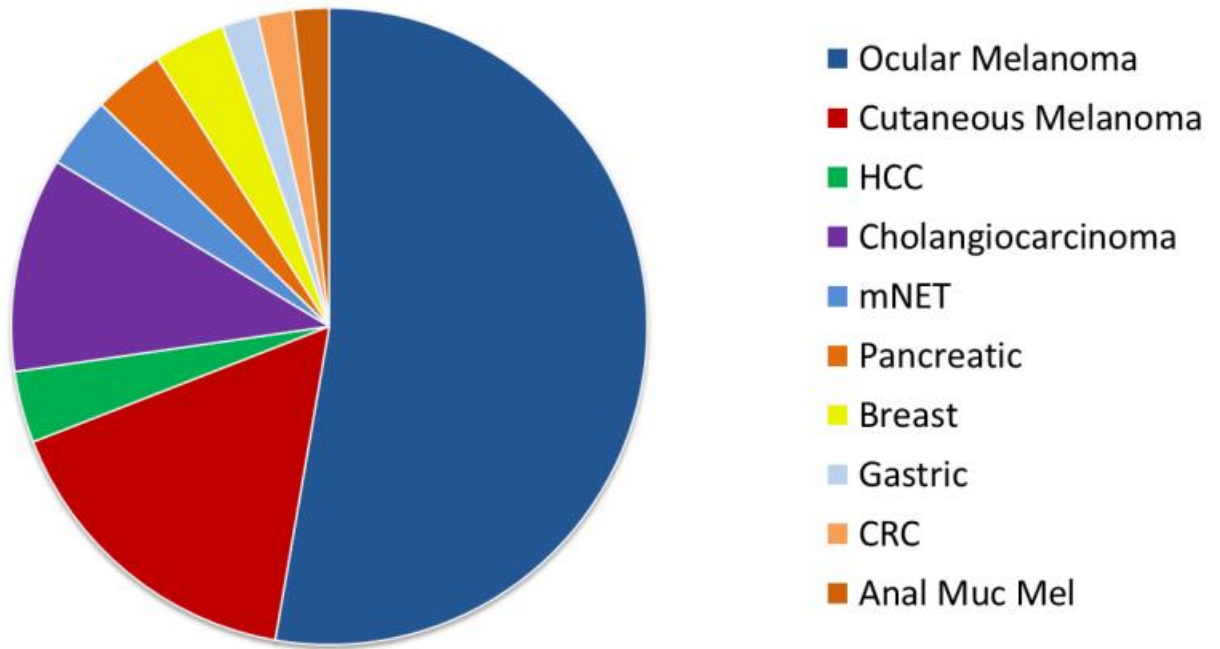
Clinical Plan to establish efficacy and safety of Mel/HDS for HCC

CHEMOSAT: Expanding Clinical Use in the EU

- § Continued commercial market access and clinical adoption activities in key EU countries
 - § Current focus on Germany, UK, Italy
- § 12 Clinical Sites treated patients in EU
- § Clinicians using CHEMOSAT for a broad range of liver metastases
 - § Including: cutaneous melanoma, ocular melanoma, colorectal cancer (CRC), gastric cancer, breast cancer, neuroendocrine tumor (NET), hepatocellular carcinoma (HCC) and cholangiocarcinoma
 - § Intend to support Investigator Initiated Trials (IITs) to further drive clinical adoption in EU markets including DE, UK, IT, NL, FR, SP

Expanding EU Clinical Adoption

CHEMOSAT: Multiple Tumor Types Treated in Europe



CHEMOSAT Treatment Sites 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

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
October 2013

NUB Decision
1 Feb 2014

DRG Code
~2 years data collection
from 1st introduction



Alternative HRG coding
to cover part of procedure

Interim Funding Submissions

- Individual funding
- National Cancer Fund
- National Care Commissioner

Block funding

- Application to fund 90 patients
- Decision Feb/2014
- 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

Multiple Capital Resources Available to Execute Plan

Cash & Cash Equivalents ~ \$28 million at September 30, 2013

Debt None

ATM Program ~ \$47 million at September 30, 2013

Committed Equity Financing Facility (CEFF) ~ \$24 million at September 30, 2013

Working Capital Line of Credit \$20 million credit facility

Shares Outstanding: ~103 million (~113 million fully diluted¹⁾ at September 30, 2013

1) Fully diluted includes an additional 4.7 million options and 5.4 million warrants

Significantly Reducing Operating Costs

Quarterly Cash Utilization:

Q1 2013 Act **\$11.3 million**

Q2 2013 Act **\$10.5 million**

Projected quarterly cash spend*:

Q3 2013 Proj **\$7-\$8 million**

Q4 2013 Proj **\$6-\$7 million**

Quarterly average 2014 Proj **\$5-\$6 million**

* Based on current projection, subject to change

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Concentrating the Power of Chemotherapy™

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APPENDIX

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LEADERSHIP TEAM



**Jennifer Simpson, Ph.D., M.S.N.,
C.R.N.P.**
Interim Co-President and Co-CEO
EVP, Global Head of Business
Operations



Graham G. Miao, Ph.D., M.S., MBA
Interim Co-President and Co-CEO,
EVP, Chief Financial Officer



Peter J. Graham
Executive Vice President,
General Counsel, Chief
Compliance Officer and Global
Human Resources



Gloria Lee, M.D., Ph.D.
Executive Vice President,
Clinical & Medical Affairs

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John Purpura
Executive Vice President
Regulatory Affairs, Quality
Assurance



Barbra Keck
Vice President, Controller &
Principal Accounting Officer

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) for PHP versus BAC analysis*
- Ø Gardner ER. *Phase 3 Randomized 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 Alexander HR. *Update of a randomized phase 3 trial of CHEMOSAT® or CS-PHP of melphalan in patients with hepatic metastases from melanoma: Phase III Randomized Controlled Analysis*
- 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”* (Submitted)
- 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”* (Submitted) 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 – In preparation*

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

§ Of which, 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

ODAC Summary

- § 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
 - § One died of neutropenic complications

- § Prophylactic growth factor support, which is used to treat neutropenia, was not protocol specified and rarely used during P2 and P3 melanoma trials
- § 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

§ One death related to myelosuppression

§ 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

EU REIMBURSEMENT – 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.

Other

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