

**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): **January 13, 2014**

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16133
(Commission File Number)

06-1245881
(IRS Employer
Identification Number)

810 Seventh Avenue, 35th 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))
-

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: January 13, 2014

By: /s/ Peter J. Graham
Name: Peter J. Graham
Title: Executive Vice President, General Counsel

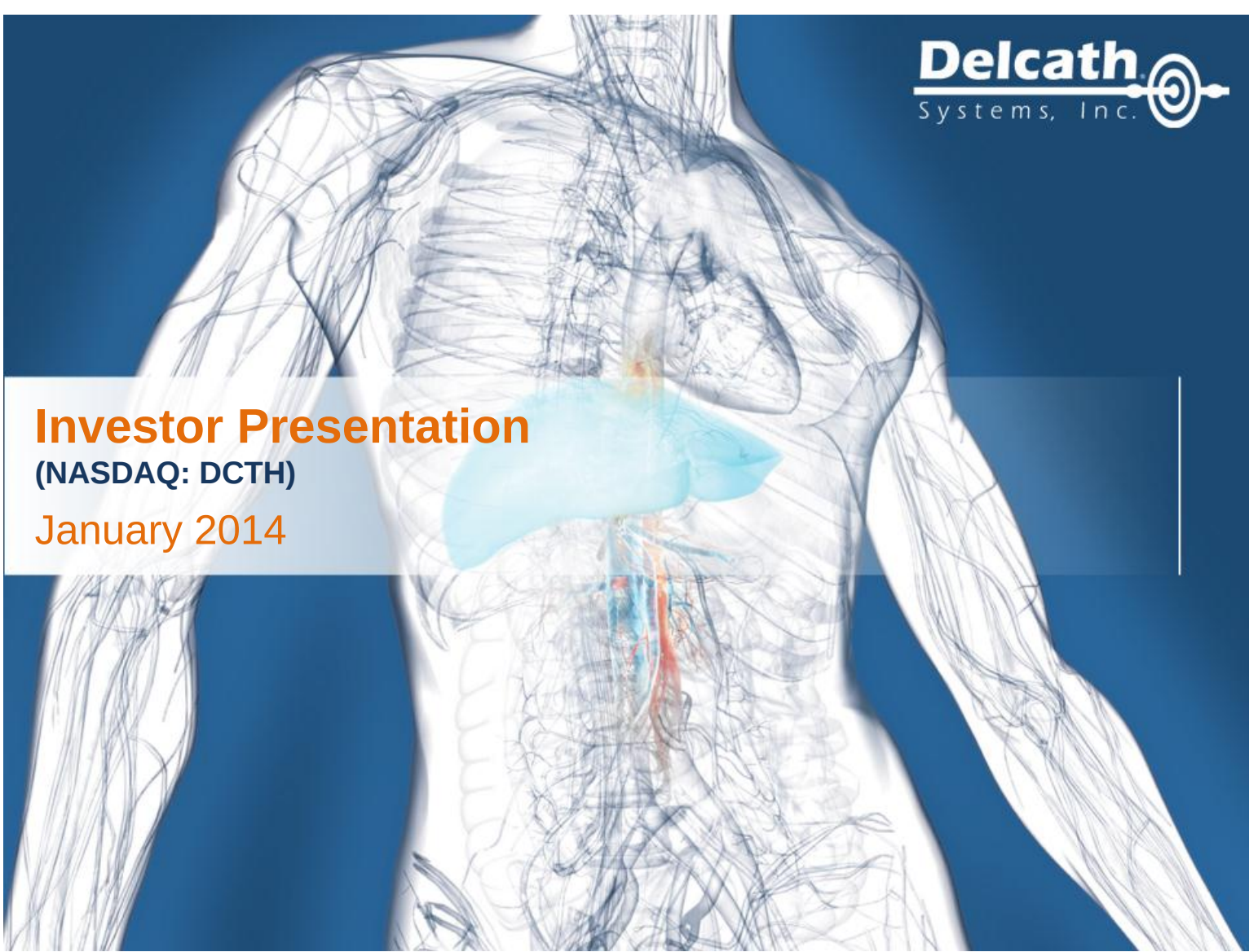
EXHIBIT INDEX

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

Investor Presentation

(NASDAQ: DCTH)

January 2014



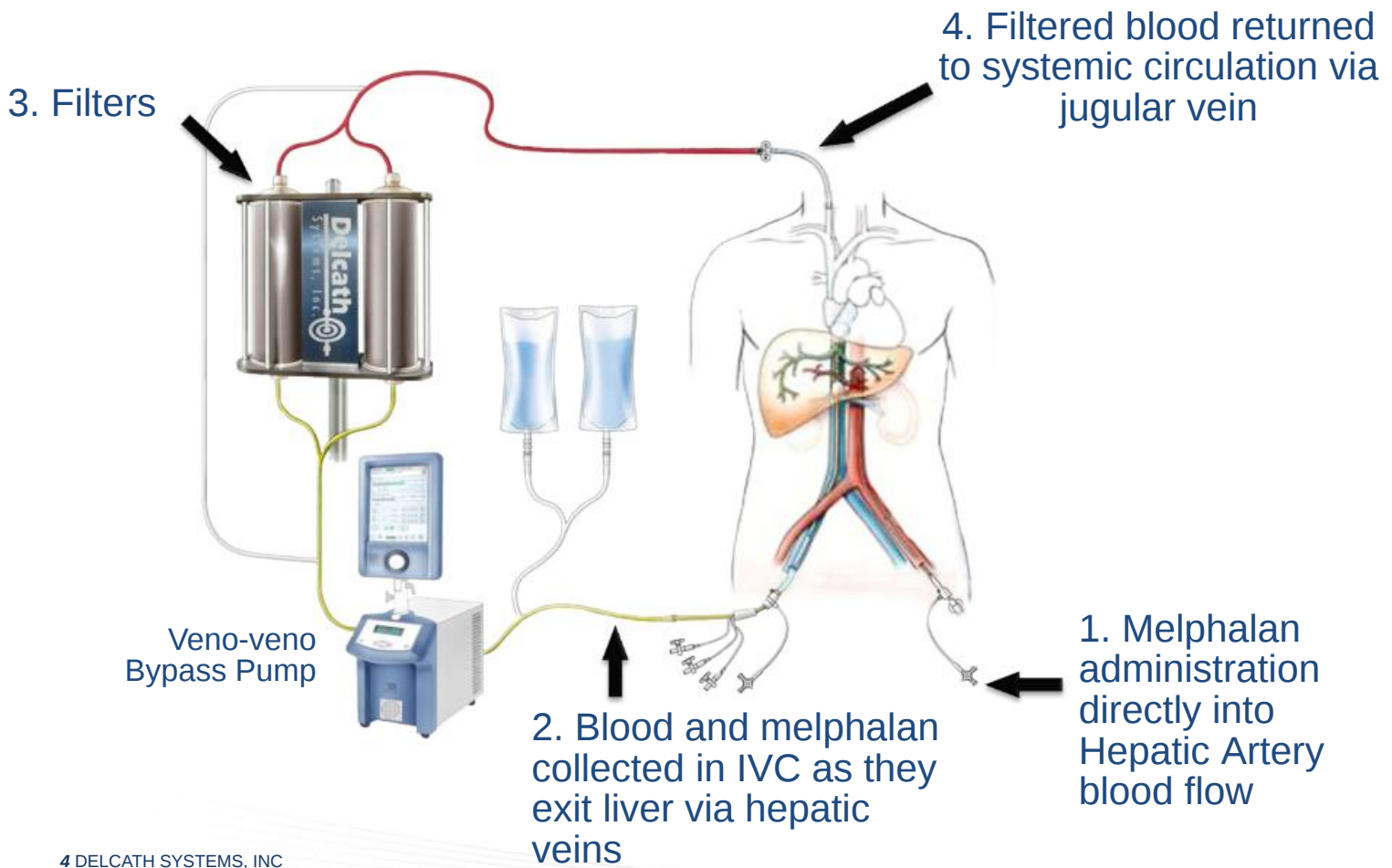
Forward-looking Statements

This presentation contains forward-looking statements, within the meaning of the federal securities laws, related to future events and future financial performance which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements that are not historical facts. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including, but not limited to, uncertainties relating to: stockholder approval of the proposed reverse stock split and the Board of Directors implementation of the same, the impact of the reverse stock split on the Company's stock price and the desired effect of a reverse stock split to regain compliance with the NASDAQ Marketplace Rules, the Company's ability to regain compliance with the NASDAQ Marketplace Rules and maintain its listing on the NASDAQ Capital market, the timing and results of future clinical trials including without limitation the Phase 2 and Phase 3 HCC trials, 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, 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, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter and the timing of the same, approval of the Melphalan HDS system by the US FDA, approval of the current or future Melphalan HDS system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same, uncertainties relating to the timing and results of research and development projects, and uncertainties regarding our ability to obtain financial and other resources for any 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 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

- § Innovative therapy addresses an underserved liver cancer market
- § Commercially available in Europe; under clinical development in the United States
- § Positive efficacy signal in multiple tumor types
- § Plan for 2014 initiation of Phase 2 clinical development program in patients with unresectable Hepatocellular Carcinoma (HCC)
- § Seeking reimbursement in key EU markets
- § Resources to support core objectives throughout 2014

The Delcath Hepatic Delivery System



EU Markets

CHEMOSAT® Hepatic Delivery System

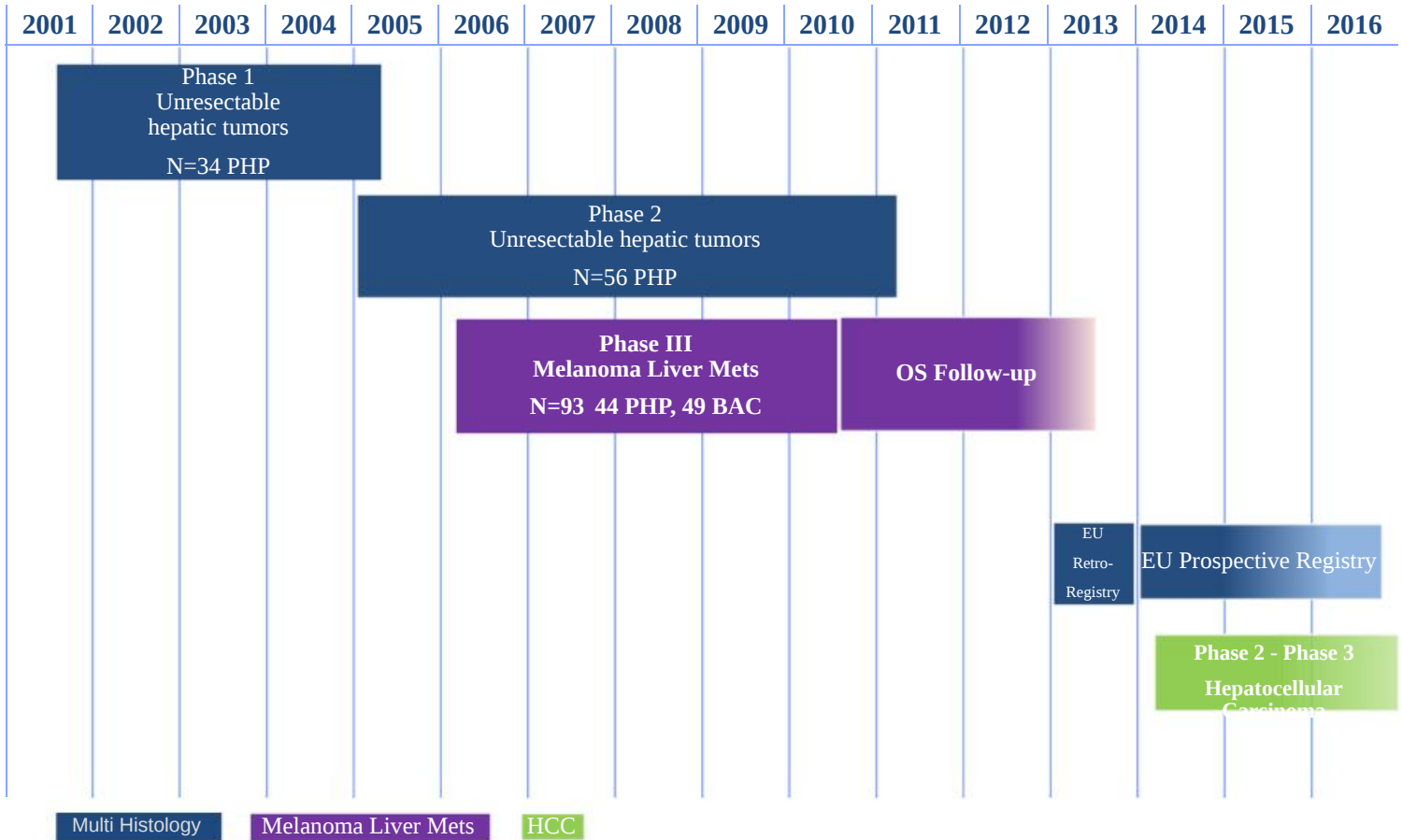
- § Regulated as a Class IIb Medical Device
- § Indicated for the intra-hepatic administration of melphalan hydrochloride and subsequent filtration of the venous blood return
- § CHEMOSAT Kit supplied without melphalan
- § In EU, the product at market access and clinical adoption stage
- § Seeking reimbursements: 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 by the FDA
- § Intend to conduct global HCC clinical program
- § Evaluating best path forward in ocular melanoma liver metastases following FDA Complete Response Letter (CRL) in September 2013

Positive Efficacy Signals in Multiple Liver Tumor Types

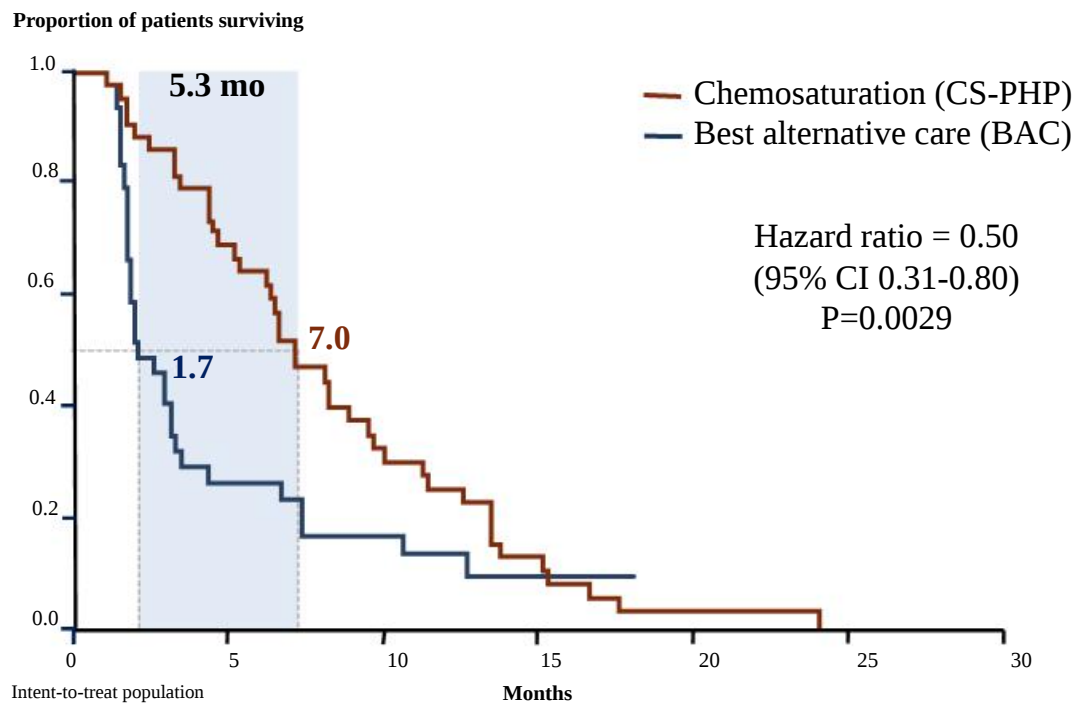


Clinically Differentiated Results

- § 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

Phase 3 Results - Primary Endpoint hPFS

Hepatic progression-free survival (IRC)

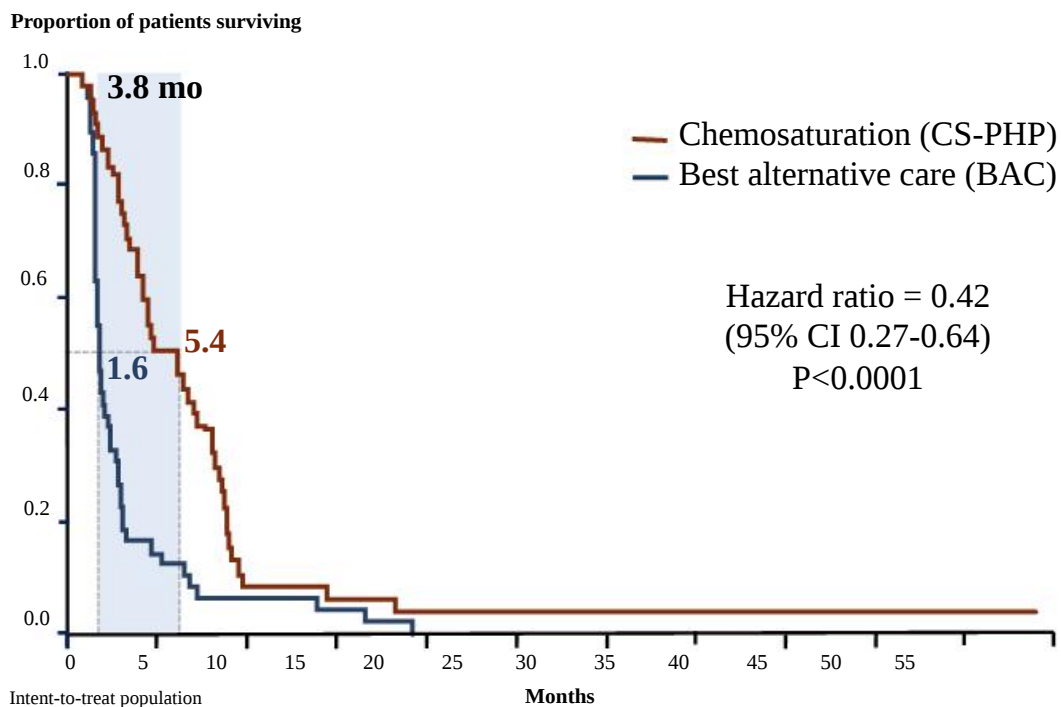


INDEPENDENT REVIEW COMMITTEE (IRC) ASSESSMENT - UPDATED ANALYSIS (4 June 2012)

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 Melphalan HDS

- § In clinical trials using early versions of the device, the integrated safety population of patients showed risks associated with Melphalan HDS to include:
 - § 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 intended to better control toxicities

FDA Complete Response Letter (CRL) on Melanoma NDA

- § Issued in 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 its risks
- § Type A Meeting Held with FDA November 2013
 - § Confirmed understanding of CRL device and procedure safety requirements
 - § Incorporating FDA feedback in current Phase 2 HCC trial design
 - § Continuing to evaluate best path forward for ocular melanoma liver metastases

Pursuing Phase 2 To Establish Proof of Concept in HCC,
Address FDA Safety Concerns Prior To Embarking On Pivotal Phase 3 Trials

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 have limitations with larger tumor burden and micro-metastases

*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 1L - 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
 - § FDA granted orphan drug designation for Mel/HDS for HCC
- § Intend to seek partners on strength of interim Phase 2 results
- § Global Pivotal Trial in HCC - to follow Phase 2 assuming positive results

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

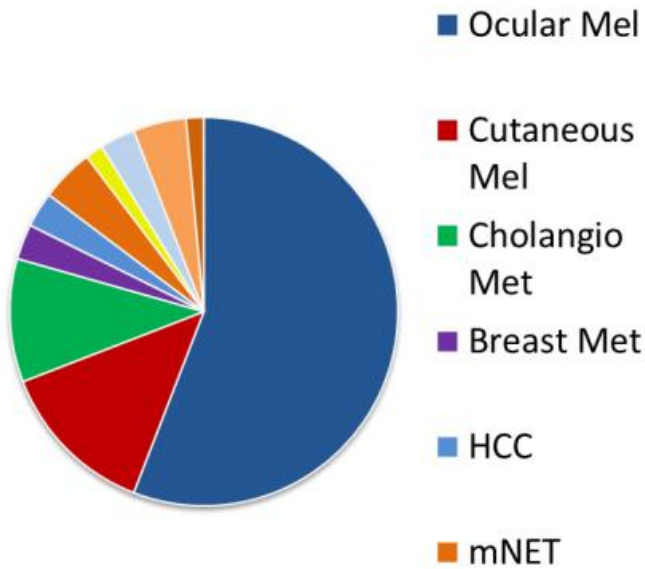
CHEMOSAT: Expanding Clinical Use in the EU

- § Continued commercial market access and clinical adoption activities in key EU countries
 - § Current focus on Germany and UK
- § 15 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 the EU

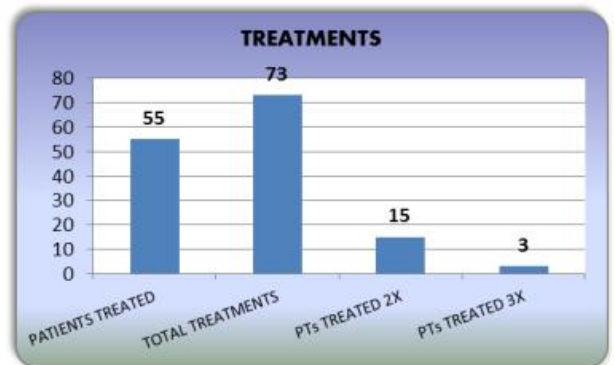
Expanding EU Clinical Adoption

CHEMOSAT: Commercial Treatments in Europe

Multiple Tumor Types Treated



Patients/Treatments



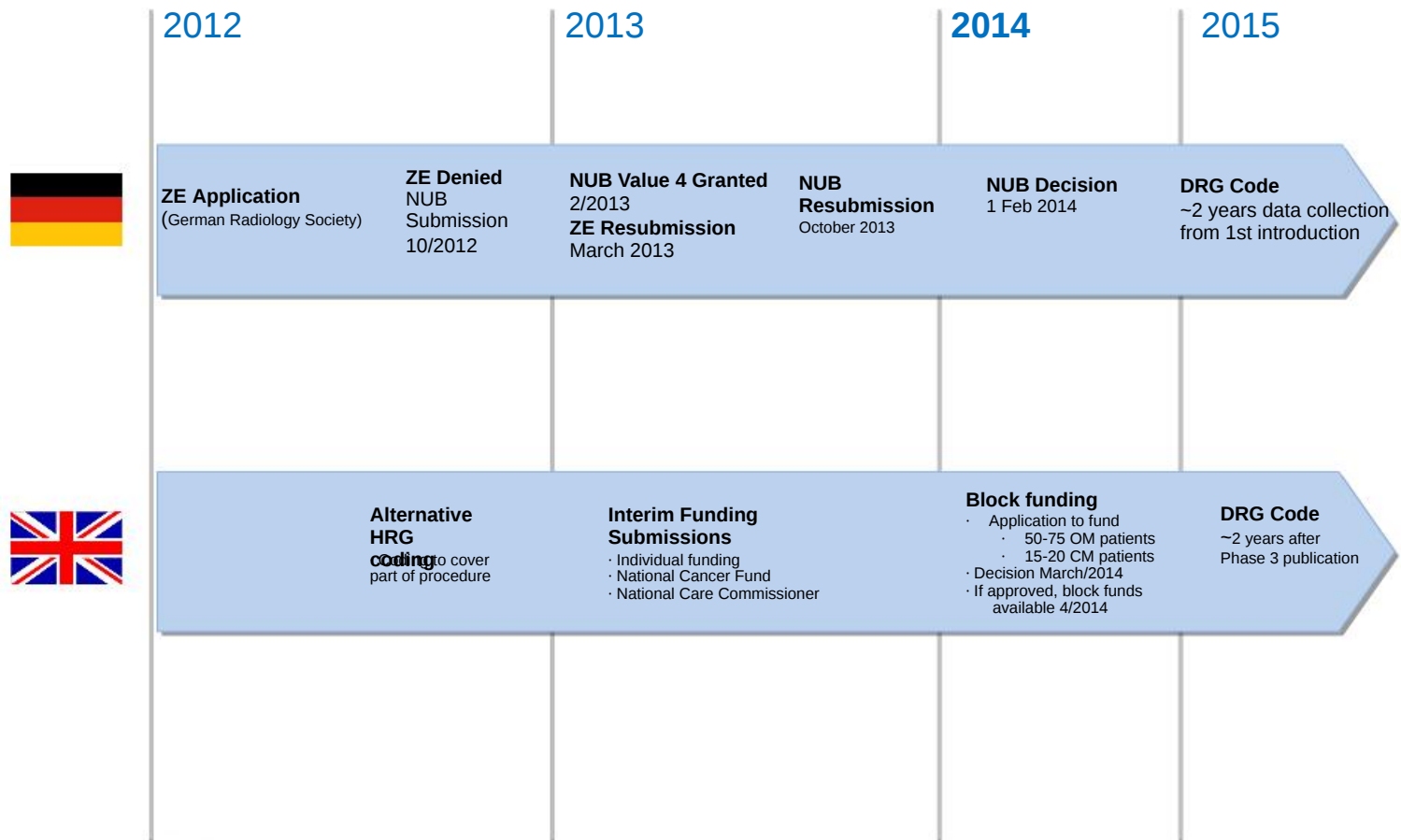
Year	2012	2013	Total
PTS	27	28	55
TX	33	40	73
2 nd TX	4	11	15
3 rd TX	2	1	3

CHEMOSAT Treatment Sites in Europe



- § University of Heidelberg Hospital
- § Berlin Charité Hospital
- § University Medical Center Göttingen
- § Johann Wolfgang Goethe-Universität
- § University of Bonn
- § Asklepios Clinic Bambek
- § Southampton University Hospital
- § SPIRE Southampton Hospital
- § European Institute of Oncology
- § Varese University Hospital
- § Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital
- § Cancer Institute Gustave Roussy
- § Hôpital Saint-André
- § Clinica Rotger Majorca Hospital
- § University Hospital Galway

EU Reimbursement Status



Multiple Capital Resources Available to Execute Plan

Cash & Cash Equivalents **\$31.2 million at December 31, 2013**

Debt **None**

ATM Program **\$44 million available at December 31, 2013**

Committed Equity Financing Facility (CEFF) **\$24 million available at December 31, 2013**

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

Shares Outstanding **134 million (153 million fully diluted^{1,2}) at December 31, 2013**

1) Fully diluted includes approximate 4 million options and 15 million warrants

2) Anticipate Feb 24, 2014 stockholder meeting seeking approval of reverse stock split to help regain NASDAQ Listing compliance

	2012	2013 (Unaudited)				2014 Guidance	
	FY	Q1 A	Q2 A	Q3 A	Q4 Est.	FY Est.	Quarterly Avg
Cash Spend		\$9-	\$9-	\$7-8M	\$6-7M		\$5-6M
Guidance		\$12M	\$12M				
Cash Spend	\$53M	\$11M	\$11M	\$7M	\$6M	\$35M	
Act./Est.							
Product Revenue	\$347K	\$81K	-	\$72K	\$338K	\$490K	

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Concentrating the Power of Chemotherapy™

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APPENDIX

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LEADERSHIP TEAM



**Jennifer Simpson, PhD., 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

- *Published in 2013*

- o *Metastatic melanoma to the liver: A contemporary and comprehensive review of surgical, systemic, and regional therapeutic options. Agarwala SS, Eggermont AM, O'Day S, Zager JS. Cancer. 2013 Dec 2.*
- o *Chemosaturation with percutaneous hepatic perfusion for unresectable metastatic melanoma or sarcoma to the liver: A single institution experience. Forster MR, Rashid OM, Perez MC, Choi J, Chaudhry T, Zager JS. J Surg Oncol. 2013 Nov 19*
- o *Isolated hepatic perfusion for metastatic melanoma. Yamamoto M, Zager JS. J Surg Oncol. 2013 Oct 25.*

- *Expected in 2014*

- o *Phase III and Phase II Publications - In preparation*
- o *Vogl, et al. "Chemosaturation with Percutaneous Hepatic Perfusions of Melphalan for Hepatic Metastases: Experience from Two European Centres" (Accepted)*
- o *Ferrucci, et al. "Experience with Generation 1 Filters vs Generation 2 Filters" (Under Review)*
- o *Alexander, et al. "Review of Percutaneous Hepatic Perfusion for Ocular Melanoma Liver Metastases" (Submitted) to be published in American Oncology and Hematology*
- o *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 winter 2014 publication)*

Abstracts Presented (2012-2013)

- 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 BAC-to-PHP crossover vs BAC-only pts
- 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 study
- Ø Gardner ER. Percutaneous hepatic perfusion (CHEMOSAT® or CS-PHP) of melphalan in patients with hepatic metastases from melanoma: Phase III pharmacokinetic analysis
- Ø Testori A. 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 Forster M. Percutaneous hepatic perfusion for unresectable melanoma or sarcoma to the liver: a single institution experience.
- Ø Testori A. Chemosaturation therapy with percutaneous hepatic perfusion for unresectable liver metastases: the European Institute of Oncology (EIO) experience.

Delcath ODAC Presentation - Summary

Full Delcath and FDA ODAC Briefing Materials Available at <http://www.delcath.com/clinical-research/clinical-bibliography/>

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

Delcath ODAC Presentation - Summary

Full Delcath and FDA ODAC Briefing Materials Available at <http://www.delcath.com/clinical-research/clinical-bibliography/>

§ 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

Delcath ODAC Presentation - Summary

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- § 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

FDA ODAC Presentation - Summary

Full Delcath and FDA ODAC Briefing Materials Available at <http://www.delcath.com/clinical-research/clinical-bibliography/>

FDA disagreed with Delcath assessment 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

In its ODAC presentation, FDA also cited concerns about periods of hypotension (low blood pressure) during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression.

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)