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): **May 17, 2013 (May 16, 2013)**

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-16133	06-1245881
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 (the "Company") presentation slides that the Company presented at the Annual Meeting of Stockholders held on May 16, 2013 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. Annual Meeting of Stockholders 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.

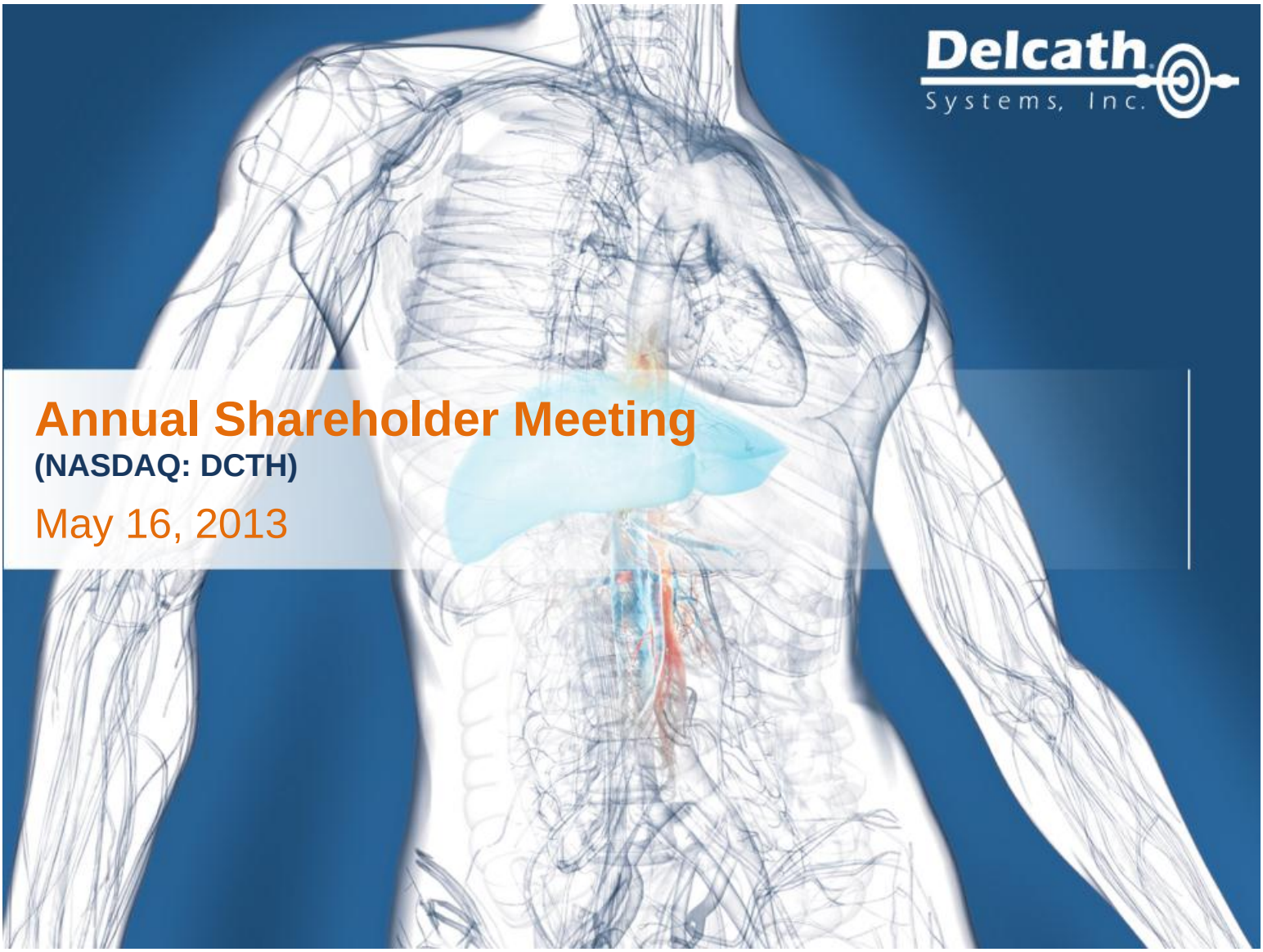
Dated: May 17, 2013

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. Annual Meeting of Stockholders Presentation Slides

Exhibit 99.1


Delcath
Systems, Inc.
Annual Shareholder Meeting
(NASDAQ: DCTH)
May 16, 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 presentation 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 PDUFA goal date extensions 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 metastatic ocular melanoma to the liver, adoption, use and resulting sales, if any, for the Melblez™ Kit *in the United States, adoption, use and resulting sales, if any, for the Hepatic CHEMOSAT Delivery System in the EEA, our ability to successfully commercialize the Melblez/CHEMOSAT System in various markets and the potential of the system as a treatment for patients with cancers in the liver, the timing and our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets including Australia and key Asian markets and resulting sales, if any, from the same, patient outcomes using the Generation 2 system, approval of the current or future system for other indications and/or for use with various chemotherapeutic agents, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system in various markets, the number of cancer centers in Germany and Italy able to successfully negotiate and receive reimbursement for the CHEMOSAT procedure and the amount of reimbursement to be provided, submission and publication of the Phase II and III clinical trial data, the timing and results of research and development projects, the timing and results of future clinical trials including the initiation of clinical trials in key Asian markets with the CHEMOSAT Hepatic Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin, approval of the CHEMOSAT Hepatic Delivery System to delver and filter doxorubicin in key Asian markets and adoption, sales, if any, and patient outcomes using the same, the timing, price and use, if any, of the committee equity financing facility with Terrapin, the timing and use, if any, of the line of credit from SVB and our ability to access this facility, the timing and use, if any, of the At-the-Market financing program, and uncertainties regarding our ability to obtain financial and other resources for any research, development 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.*

Product Status

US Market

- Proposed Trade Name

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

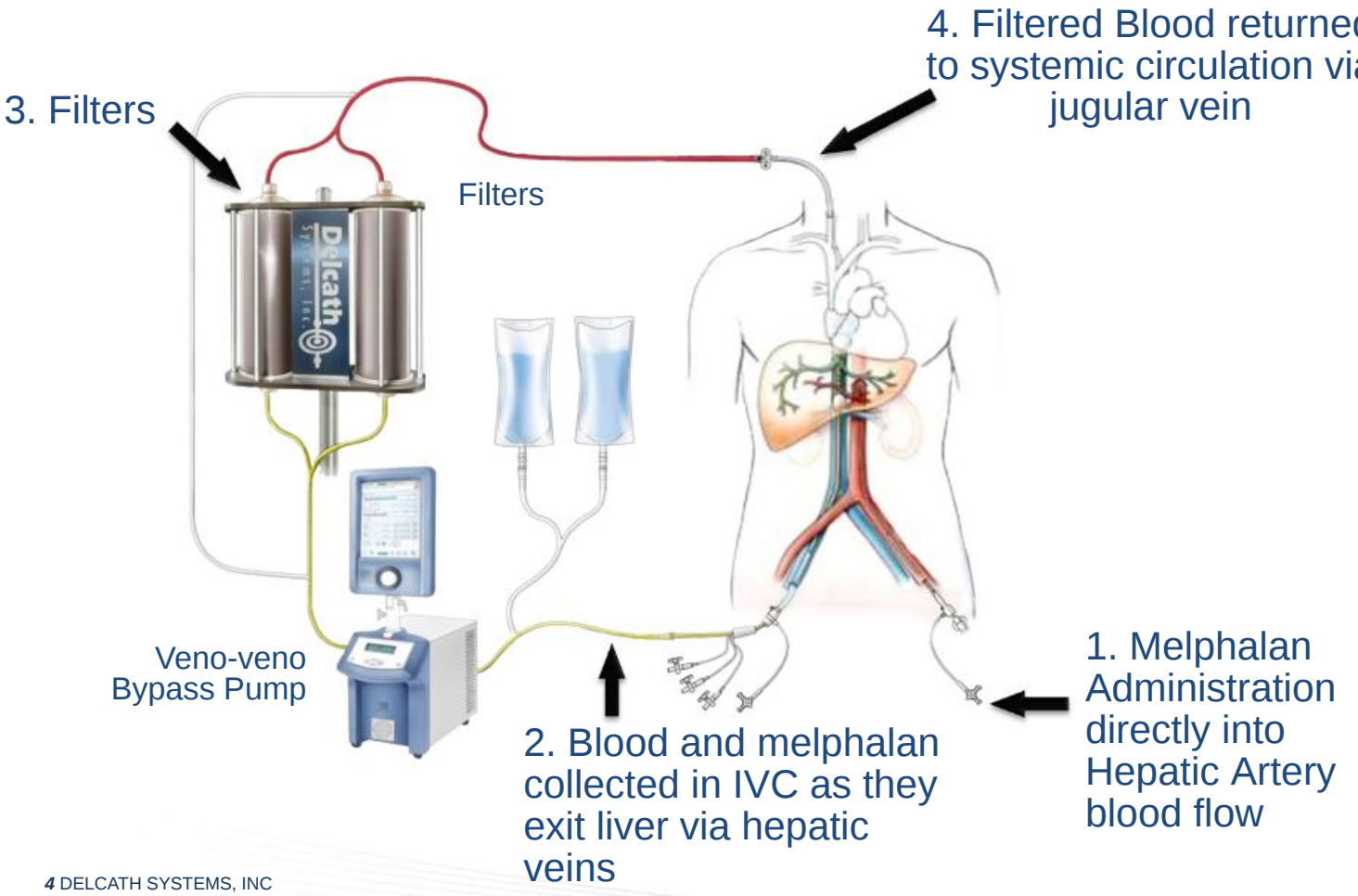
Ex US Markets

- Marketed under the trade name

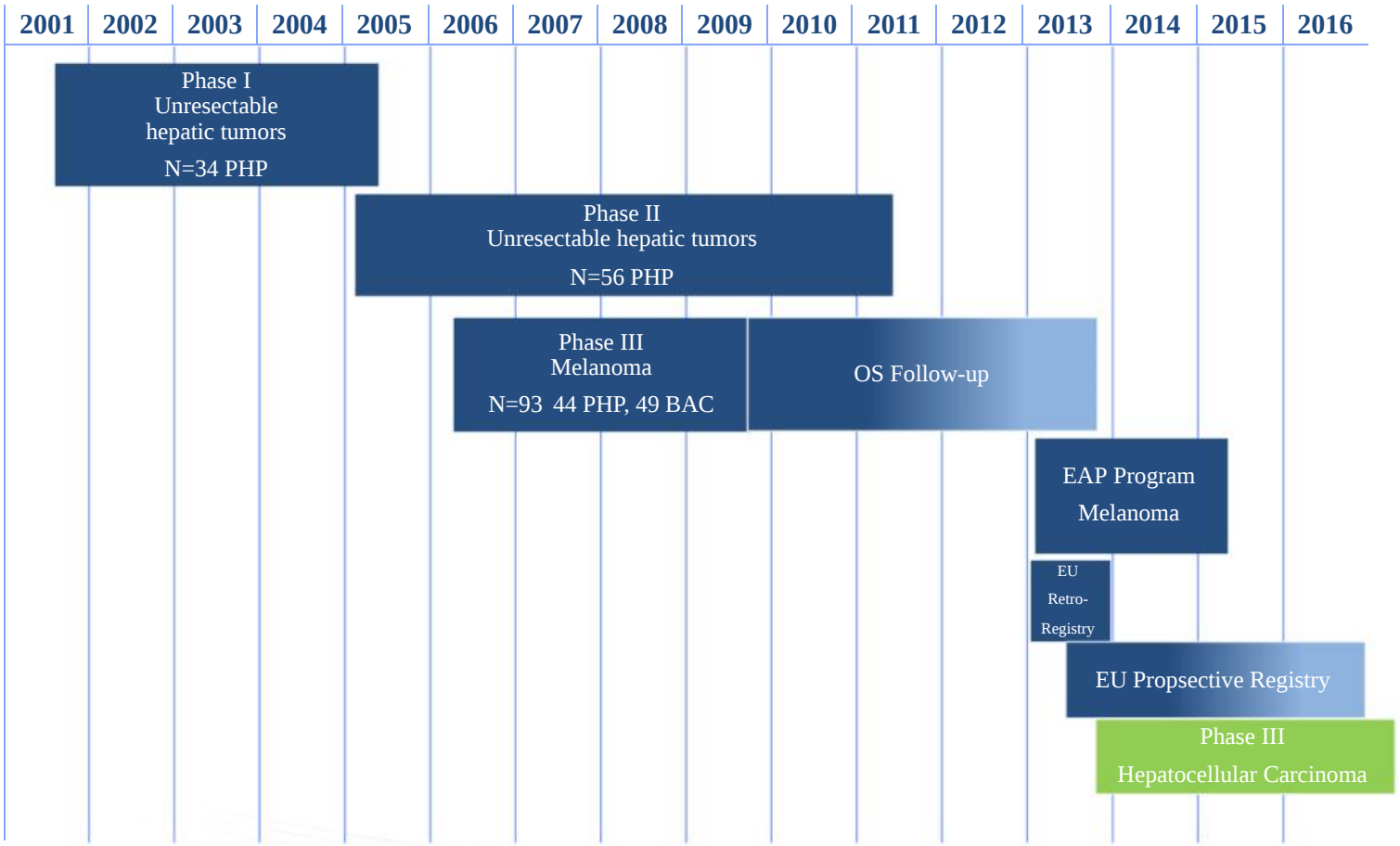
CHEMOSAT® Hepatic Delivery System

- 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

How the Combination Product Works



Clinical Program



ODAC – U.S. NDA Still Under Review

- Oncology Drug Advisory Committee (ODAC) negative vote based on Gen 1 Data
- NDA filing included:
  - Gen 2 filter contained in the Chemistry, Manufacturing and Control (CMC) module as a technical change
- Waiting for FDA Clarification of what additional Gen 2 clinical data is required
  - Actively collecting Gen 2 Clinical Data
    - § US EAP (melanoma)
    - § EU Retrospective & Prospective Registries (mixed histologies)
- PDUFA Goal Date: September 13, 2013
- Initial indication: seeking unresectable metastatic ocular melanoma in the liver

FDA Decision Expected in September

ODAC Patient Letter

To: Caleb Briggs , Pharm.D.
Designated Federal Officer , Oncologic Drugs Advisory Committee

From: Debbie Molzberger

Subject: ODAC Application # 201848

I was diagnosed with ocular melanoma in 2001 at age 49. I had perfect health all of my life, no family history of melanoma, perfect vision and no reason to be concerned about a serious health problem except I slowly began to notice I was could not see well out of my right eye. I first noticed the vision problem around Christmas of 2000. I went to my family doctor , to a well respected optometrist and to the opthamologist between January and April of 2001. No one could find anything wrong and I was told it is typical to have less than perfect vision as we age so I bought a pair of reading glasses and went about my life. In June I started having sharp pain in my right eye and my vision was getting worse. I went back to my PCP and explained what I was experiencing. I am very in tune with my body, and now my body was screaming that something was terribly wrong. Thank God my doctor cared and really listened to me. He referred me to Dr. Don Jacobs at the Cincinnati Eye Institute. Dr. Jacobs discovered a small tumor was growing around the optic nerve.I was sent to several more doctors and finally received the horrific diagnosis that I had ocular melanoma and there was no cure. I was offered the option of a radition plaque insert or the enuculation of my right eye. We felt that my best chance was to go with the enuculation. The surgery was a success and it was not until 2005 that the first METASTASIS was discovered in my right lung , followed in 2008 by a metastsis to the liver. Throughout the years I participared in many drug trials, had the right lower lobe of my lung resectioned and although the cancer in my right lung was controlled very well, the cancer in my liver was growing rapidly. Luckily in the summer of 2009 CNBC and CNN News reported on an amazing cancer trial for metastatic liver cancer caused by ocular melanoma. It was being conducted at The University of Maryland under Dr. H Richard Alexander. The trial was sponsored by Delcath Systems, Inc. using the chemotheraphy drug melphalan - we refered to it as PHP.

My oncologist in Cincinnati, Ohio , Dr. Phlip Leming contacted Dr. Alexander and I had my first consultation in June 2009.Due to study guidelines I was not selected to participate in June , but after new scans in August 2009 showed the tumors continued to grow aggresively, I was accepted in to the trial immediately and had my first PHP treatment in August of 2009 and a second treatment in late September 2009. The treatments were hard but by Thanksgiving I felt great. The cancer in my liver was gone. Subsequent scans over the next 23 months indicated that the liver was normal and " unremarkable." Sadly, the scans in August 2011 showed a shadow on the liver and by November 2011, I was told the cancer had returned. Before I go any further with my story , please let me tell you that I have had excellent quality of life and most of all , every day that I wake up and experience one more day of living this incredible thing called life - there is simply no word to express my gratitude, my joy and happiness. After the cancer returned in November of 2011 I have had a liver ablation, a chemoemolazation , participated in a trial at Dana Farber of AEB01, and had three treatments of Yervoy. Unfortunately nothing helped and the cancer advanced significantly. The PHP trial in Baltimore was now closed and there was not an opportunity to have another treatment in the United States.I knew that was the treatment that worked. Can you imagine how frusterated we were knowing we could not have this treatment again without leaving our country?

In September of 2012 we contacted Dr. Alexander again and went to Baltimore for a consultation in hopes we could somehow find away to get permission to have another PHP treatment. Dr. Alexander, the University of Maryland and Delcath Systems worked together on my behalf and finally on February 20, 2013 I did have another treatment of NDA201848 .But the question that haunts me day and night now is this : what if I could have had another PHP treatment in November 2011 imediately after we discovered the cancer had returned, before the cancer in my liver had grown so large and become so aggresive. If only the # NDA20148 was approved as " standard of care " how many people would still be here living full, meaninhful lives?

The NDA201848 has already prolonged my life for almost four years ! Two of those years I was in stable condition with no detectable disease in the liver ! The quality of life, the amount of life, how can I , as a patient express to you what this time has meant to me, my beloved husband and our children? This treatment works. It is prolonging lives here and in other countries. There is nothing else in the ocular melanoma world has that can give patients these results. It is constantly in my prayers that as science learns to prolong lives for people with rare, incurable cancers, someday the actual cure will be found.

As a person who has lived with ocular melanoma for almost 13 years , I ask , I beg the FDA to approve this treatment. People with rare,difficult cancers deserve the opportunity to live quality, happy lives as long as possible.

With Genuine Hope and Trust,

Debbie Molzberger

ODAC Briefing Materials Available on Website

Delcath Systems, Inc.

HOME | ABOUT US | THE TECHNOLOGY | CLINICAL RESEARCH | INVESTORS | NEWS & EVENTS

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Clinical Bibliography

- ABOUT CLINICAL TRIALS
- TRIAL ENROLLMENT INFORMATION
- COMPLETED CLINICAL TRIALS
- ONGOING CLINICAL TRIALS
- CLINICAL BIBLIOGRAPHY ›

View and download from our library of clinical trial articles and other publications. Opening PDFs requires Adobe® Reader® to be installed on your computer. Download Adobe's latest version of this free program here.

Oncology Drug Advisory Committee Briefing Materials
Melblez Kit™, May 2, 2013

- Delcath Briefing Information
  FDA Briefing Information
- Delcath ODAC Presentations
  FDA ODAC Presentations

Articles

- Gilcher RO. Additional separate report on analysis of porcine PHP procedures using Delcath gen 2 filters. Report.
- Deneve JL. Chemosaturation with Percutaneous Hepatic Perfusion for Unresectable Isolated Hepatic Metastases from Sarcoma. *Cardiovasc Intervent Radiol*. 2012 Jun 15. [Epub ahead of print]
- Zager J. Therapeutic options for regionally metastatic melanoma: Isolated limb infusion and Chemosaturation - percutaneous hepatic perfusion. *Clinical and Experimental Metastases*. 2012. In press.

Phase 2 NCI Trial – Hepatobiliary Carcinoma Cohort

- Best hepatic tumor response by modified RECIST assessed by investigators
  - Partial response (PR) 1 patient
  - Stable disease (SD) 4 patients
  - Progressive disease 1 patient
  - Not assessed or evaluable 2 patients
- Median duration of response
  - hPR (N=1) 6.42 months
  - hPR/SD (N=5) 8.12 months
- Hepatic progression free survival (ITT N=8)
  - Median 5.60 months
  - Minimum, Maximum 2.7, 12.2 months
- Overall survival (ITT N=8)
  - Median 9.12 months
  - Minimum, Maximum 3.4, 20.5 months
- HCC is the most common primary cancer of the liver, with approximately 750,000* new cases diagnosed worldwide annually
- Intend to initiate new Phase 3 trial in HCC in 2013
  - Met with FDA and obtained feedback on trial design

*Source: GLOBOCAN

Encouraging Positive Signal for Primary Liver Cancer

HCC Opportunity

- Large U.S. & Global Market
- Liver centric disease, liver centric treatment
- Unmet need in 2L therapies
- Clinical Trial Design:
  - Gen 2 Filter
  - OS primary endpoint
  - No Crossover – clear OS data
  - QoL data collection
- Expect Improved Safety over P2 & P3 trials:
  - P2 & P3 Protocol amendments, REMS training, and Gen 2 CHEMOSAT System are demonstrating significantly improved safety in US EAP and EU Commercial Use

HCC – Global Market Opportunity Estimate

Market	# Patients	Potential # Procedures	Potential Market ($MM)[1,2,3]
United States	5,586	13,964	$ 1,047
Europe	7,671	19,177	$277
APAC	99,749	249,373	$ 1,156
TOTAL	113,006	282,514	$2,480

Sources: LEK Consulting, GLOBOCAN, Company estimates.

1) Assume 2.5 treatments per patient.
2) US Assumes ASP of ~$75K USD
3) EU Assumes ASP of ~$15K USD; mix of direct/distributor pricing
4) APAC Assumes ASP of ~$5K USD; device only

Attractive U.S. & Global HCC Market Opportunity

US Market by Disease – Device and Drug Combination

Liver Metastasis	Potential Market # Patients	Potential Market # Procedures	Potential Market ($MM)[1,2,3]
Ocular Melanoma	**1,685**	**4,213**	**$ 300**
HCC (Primary)	5,586	13,964	$ 1,047
CRC	19,861	49,653	$ 1,241
NET	8,212	20,530	$ 513
Cutaneous Melanoma	**7,023**	**17,557**	**$ 439**
TOTAL	**42,367**	**105,917**	**$ 3,540**

Sources: LEK Consulting, GLOBOCAN, Company estimates.
1) Assume 2.5 treatments per patient.
2) Assume ASP of $75K for Ocular Melanoma/HCC (estimated orphan drug pricing)
3) Assume ASP of $25K in Cutaneous Melanoma, CRC, NET

Europe Market by Disease – Device Only

	Germany (Direct)	UK (Direct)	France (Indirect)	Italy (Indirect)	Spain (Indirect)	Netherlands (Direct)	Ireland (Direct)	Total Potential (patients)	Potential Market ($ MM)[1,2,3]
Total Potential Market #Patients									
Ocular Melanoma	404	297	295	285	197	79	19	1,576	$ 62
Cutaneous Melanoma	1,625	994	753	801	360	379	73	4,987	$ 206
HCC (Primary)	1,637	720	1,514	2,597	1,087	82	35	7,671	$277
CRC	9,902	5,300	5,475	7,281	4,016	1,644	335	33,953	$1,339
NET	1,783	1,336	1,353	1,299	974	360	98	7,202	$ 281
TOTAL	**15,351**	**8,647**	**9,389**	**12,263**	**6,634**	**2,545**	**560**	**55,389**	**$ 2,166**

Sources: LEK Consulting, GLOBOCAN, Company estimates.
1) Assumes 2.5 treatments per patient.
2) Assumes ASP of ~$15K USD.
3) Assumes mix of direct sales and distributors.

Europe Presents Significant Potential Market Opportunity

APAC Market by Disease

	China (Device)	S. Korea (Device)	Japan (Device)	Taiwan (Device)	Australia (Device)	Total Potential (patients)	Potential Market ($MM)[1,2]
Total Potential Market #Patients							
HCC (Primary)	**85,780**	**3,258**	**8,296**	**2,152**	**263**	**99,749**	**$ 1,156**
Other							
CRC	31,127	3,245	14,298	1,441	2,031	**52,143**	**$ 642**
NET	29,197	1,048	2,759	500	462	**33,966**	**$ 393**
Ocular Melanoma	1,765	66	175	31	96	**2,134**	**$ 25**
Cutaneous Melanoma	382	43	136	246	1,144	**1,951**	**$ 23**
OTHER TOTAL	**62,472**	**4,403**	**17,368**	**2,218**	**3,733**	**90,194**	**$ 1,083**
TOTAL	**148,104**	**7,661**	**25,665**	**4,370**	**3,996**	**189,943**	**$ 2,239**

Sources: LEK Consulting, GLOBOCAN, Company estimates.
1) Assume 2.5 treatments per patient.
2) Estimated ASP of ~$5K.

APAC Target Markets Represent Over $2 Billion Potential Market Opportunity

2013 Clinical Development Plan

Hepatocellular carcinoma (HCC) Trial Design:

Global Phase 3 Randomized (1:1) CHEMOSAT/MELBLEZ Melphalan vs. best supportive care (BSC) for patients who have failed Sorafenib (or are intolerant due to unacceptable toxicity)

- Primary endpoint: Overall Survival w/no crossover
- Secondary endpoints: hPFS, hORR, extra-hepatic PFS
- Exploratory analysis: QoL

- Planned, small phase 2 studies including Investigator-initiated trials (IITs) in multiple indications: HCC, NET, CRC, Melanoma

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

Additional Clinical Data Generation

- Goals:
  - Expand US (PHP: MEL) label indications beyond the initial indication we are seeking
  - Generate robust clinical data to support commercialization
- FDA has accepted IND Amendment that includes Gen 2 device in US Expanded Access Program (EAP), compassionate use (CU), and all future clinical trials
- Initiated US EAP with Gen 2 to treat first patient in January, 2013; 2 patients treated (1 twice), 4 additional currently scheduled
- Activate EU Registries to systematically collect Gen 2 data from commercial experience
- Include Taiwan Partner Chi Fu in Global HCC P3 trial

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

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 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 Preston 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 Orsi F. *Role of regional therapies compared with advances in systemic treatment for melanoma*

New Publications in 2012

- Deneve, Jeremiah L., et al. "Chemosaturation with Percutaneous Hepatic Perfusion for Unresectable Isolated Hepatic Metastases from Sarcoma." ***Cardiovasc Intervent Radiol* (2012)**
- Leong, Stanley PL, et al. "Progression of Cutaneous Melanoma: Implications for Treatment." **Clin Exp Metastasis (2012)**

Chemosaturation with Percutaneous Hepatic Perfusion for Unresectable Isolated Hepatic Metastases from Sarcoma

Progression of cutaneous melanoma: implications for treatment

A Glimpse of 2013 Publications Thus Far

- Publications
  - *Uzgare RP, et al. Evaluation of melphalan, oxaliplatin, and paclitaxel in colon, liver, and gastric cancer cell lines in a short-term exposure model of chemosaturation therapy by percutaneous hepatic perfusion. Anticancer Research. 2013;33:1989-2000*
  - *Rojo German publication – submission pending*

ANTICANCER RESEARCH *33*: 1989-2000 (2013)

Evaluation of Melphalan, Oxaliplatin, and Paclitaxel in Colon, Liver, and Gastric Cancer Cell Lines in a Short-term Exposure Model of Chemosaturation Therapy by Percutaneous Hepatic Perfusion

RAJNEESH P. UZGARE, TIMOTHY P. SHEETS and DANIEL S. JOHNSTON

Pharmaceutical Research and Development, Delcath Systems, Inc., Queensbury, NY, U.S.A.

Abstract. *Background: The goal of this study was to determine whether liver, gastric, or colonic cancer may be suitable targets for chemosaturation therapy with percutaneous hepatic perfusion (CS-PHP) and to assess the feasibility of utilizing other cytotoxic agents besides melphalan in the CS-PHP system. Materials and Methods: Forty human cell lines were screened against three cytotoxic chemotherapeutic agents. Specifically, the dose-dependent effect of melphalan, oxaliplatin, and paclitaxel on proliferation and apoptosis in each cell line was evaluated. These agents were also evaluated for their ability to induce apoptosis in normal primary human hepatocytes. A high-dose short-term drug exposure protocol was employed to simulate conditions encountered during CS-PHP. Results: The average concentration of melphalan required for inducing significant apoptosis was 63 μM, or about 3-fold less than the theoretical concentration of 192 μM, achieved in the hepatic artery during CS-PHP dosing with melphalan. Additionally, we found that gastric cancer cell lines were 2-5 fold more sensitive to apoptosis than liver cancer cell lines to all three compounds, suggesting that in addition to colonic and gastric cancer metastases to the liver, primary gastric cancer may also be amenable to management by CS-PHP using an appropriate therapeutic agent. Significantly, at concentrations that are predicted using the CS-PHP system, these agents caused apoptosis of colonic, gastric, and liver cancer cells but were not toxic to primary human hepatocytes. Conclusion: The compounds tested are potential candidates for use in the CS-PHP system to treat patients with gastric and colonic metastases, and primary cancer of the liver.*

Correspondence to: Rajneesh P. Uzgare, Ph.D., Director of Pharmaceutical Research, Delcath Systems, Inc., 566 Queensbury Avenue, Queensbury, NY 12804, U.S.A. Tel: +1 5187438892 ext. 349, Fax: +1 5187430139, e-mail: ruzgare@delcath.com

Key Words: Chemosaturation therapy, percutaneous hepatic perfusion, melphalan, taxanes, platinum agents.

0250-7005/2013 $2.00+.40

Chemotherapeutic molecules exert beneficial clinical effects by inhibiting cell growth or by inducing cell death via apoptosis. They can be divided into several categories based on their mechanisms of action. The chemotherapeutic agent melphalan hydrochloride, which has been approved by the US Food and Drug Administration and is used in the treatment of multiple myeloma and ovarian cancer, is a derivative of nitrogen mustard that acts as a bifunctional alkylating agent. Melphalan causes the alkylation of DNA at the N-7 position of guanine and the N-3 position of adenine (1). Thus, the binding of melphalan to DNA can result in cross-linking between bases, particularly G-G and G-A, on complementary strands, which leads to double-stranded DNA breaks and cell death through a caspase-mediated apoptotic pathway (2-5). Taxanes, such as paclitaxel, exert their effects by inhibiting microtubules (6, 7). Disruption of microtubules during cell division leads to cell-cycle arrest and subsequent cell death by apoptosis. Paclitaxel has been used clinically in treatment regimens for a number of cancer types such as breast cancer and non-small-cell lung cancer (8). Platinum agents, such as oxaliplatin, bind to and damage DNA, which leads to disruption of transcription and replication and to cell-cycle arrest. If this DNA damage is not repaired, apoptosis will ultimately result (9). These agents comprise part of the treatment regimens for cancer such as colorectal, ovarian, and bladder cancer (10).

At the doses required for clinical efficacy, chemotherapeutic agents are often associated with significant side effects. For example, because these compounds target rapidly dividing cells, they often induce myelosuppression, which contributes significantly to patient morbidity (11). Thus, a system that enables the delivery of chemotherapeutic compounds specifically to the organ of interest while reducing systemic

2013 Abstracts

- 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*" To be published in American Oncology and Hematology
- Zager, J. *"Moffitt Cancer Center Experience with PHP", submission pending*
- *Phase III and Phase II Publications – final stages of review*

CHEMOSAT: EU Commercial Launch Underway

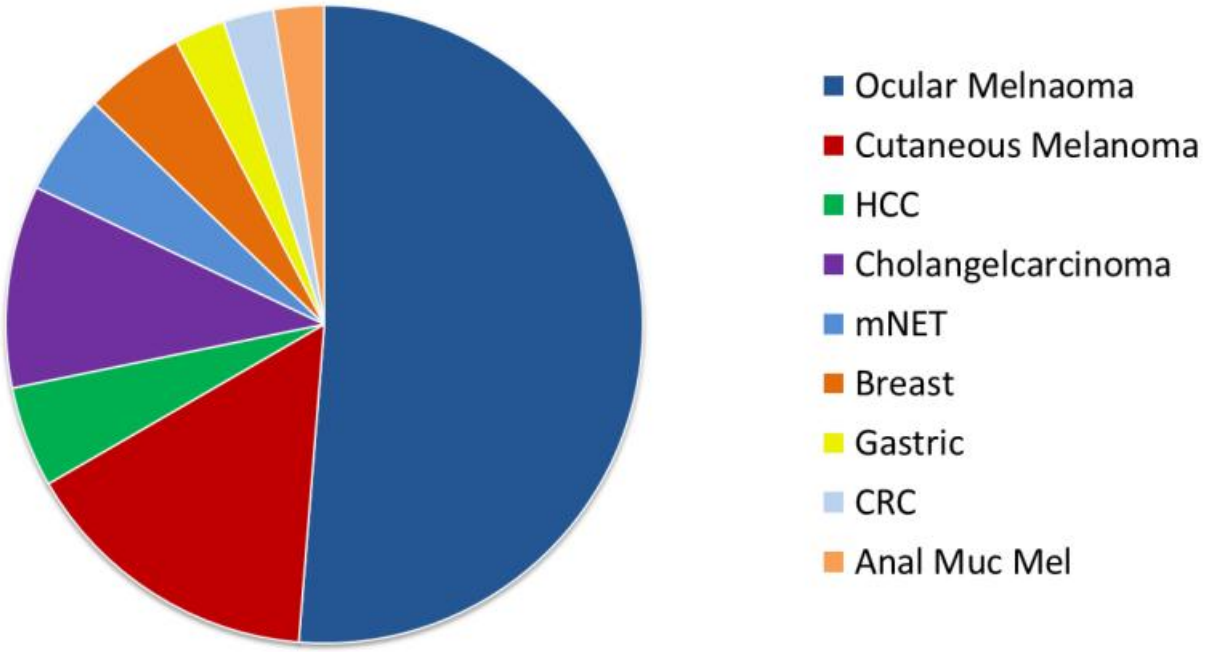
- Marketing in target EU countries – Italy, Germany, France, UK, Ireland, NL, Spain
- Training completed in key centers
  - Nine EU Clinical Sites activated as of March, 2013
- EU clinicians using CHEMOSAT for a broad range of liver metastases
  - Use includes: cutaneous melanoma, ocular melanoma, colorectal cancer (CRC), gastric cancer, breast cancer, neuroendocrine tumor (NET), hepatocellular carcinoma (HCC) and Cholangiocarcinoma
- EU reimbursement: work in progress
  - Italy – Existing DRG for partial reimbursement identified; supplemental reimbursement applications submitted
  - Germany – Value 4 NUB interim reimbursement pathway granted February 2013
  - UK – Reimbursement anticipated Q2 2013

Expanding EU Clinical and Commercial Footprint

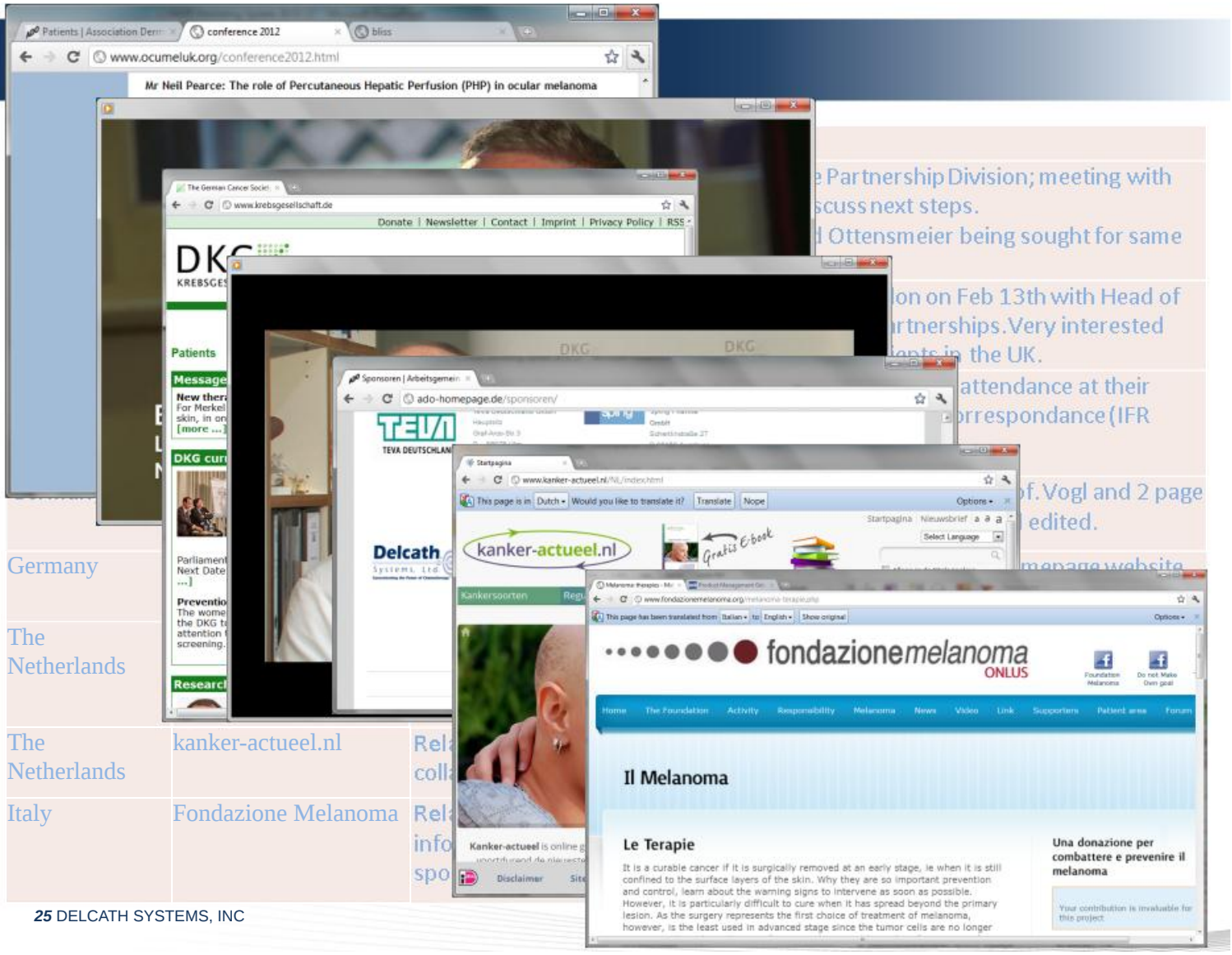
Active CHEMOSAT Centers in Europe

- **Milan, Italy – European Institute of Oncology (IEO)**
- **Frankfurt, Germany – Johann Wolfgang Goethe-Universität (JWG)**
- **Villejuif, France – Cancer Institute Gustave Roussy (IGR)**
- **Bordeaux, France – Hôpital Saint-André (St Andre)**
- **Galway, Ireland – University Hospital Galway (UHG)**
- **Southampton, United Kingdom – Southampton University Hospital (SUH)**
- **Göttingen, Germany – University Medical Center Göttingen (UMG)**
- **Varese, Italy – Varese University Hospital (VUH)**
- **Amsterdam, The Netherlands – Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital (NKI)**

CHEMOSAT: Multiple Tumor Types Treated in Europe



- Physicians are recognizing the potential of CHEMOSAT in various tumor types
- CHEMOSAT utilized in Germany, Italy, UK, France, Ireland, and the Netherlands
- EU Retrospective Data Collection to be initiated in Q2
- EU Prospective Registry To Be Initiated Q3



Germany		
The Netherlands		
The Netherlands	kanker-actueel.nl	Rela coll
Italy	Fondazione Melanoma	Rela info spo

Partnership Division; meeting with
scuss next steps.
Ottensmeier being sought for same

on on Feb 13th with Head of
rtnerships. Very interested
the UK.
attendance at their
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f. Vogl and 2 page
edited.

mepage website

EU Coverage – Excerpts

Mail Online

Breakthrough cancer treatment could prolong life by bathing just one organ in chemotherapy

- **First time patients in UK have received chemotherapy treatment on just one organ**
- **U.S study found patients who had new 'PHP' treatment survived five times longer before the disease spread compared to those on standard treatment**

By CLAIRE BATES

BBC NEWS WORLD

First liver cancer 'chemo-bath' in the UK

By James Gallagher
Health and science reporter, BBC News

Dr Brian Stedman, a consultant interventional radiologist, said: "To cut off an organ from the body for 60 minutes, soak it in a high dose of drug and then filter the blood almost completely clean before returning is truly groundbreaking.

"Previously, the outlook for patients specifically suffering from cancer which has spread to the liver has been poor because standard chemotherapy's effect is limited by the unwanted damage the drug causes to the rest of the body."

Dr Stedman told the BBC: "In 20 years' time the idea of injecting a drug which poisons the whole body for a cancer in just one small area will seem bonkers."

Cancer Drug News

Chemosaturation demonstrates clinically-meaningful tumour response in MNET

At the 2011 Cardiovascular and Interventional Radiological Society of Europe (CIRSE) congress, being held from 10th to 14th September, in Munich, Germany, updated results from the metastatic neuroendocrine tumour (MNET) cohort of Delcath Systems' recently-completed Phase II trial were presented.

In the trial's MNET cohort, 24 patients with unresectable MNET in the liver underwent an average of three chemosaturation procedures with concentrated melphalan and subsequent extra-corporeal venous haemofiltration. The primary endpoint of overall hepatic response rate among the 20 evaluable patients was 70 per cent, including one who presented with a confirmed complete response and 13 with confirmed partial responses. Four patients had stable disease and two progressed at their first evaluation, giving a tumour growth control rate of 90 per cent. As for secondary endpoints, the median overall survival in all 24 patients (on an

Mail Online

Treatment that could transform prospects for desperately ill patients

By DAVID HURST

PUBLISHED: 19:59 EST, 7 January 2013 | **UPDATED:** 19:59 EST, 7 January 2013

Looking at me, you'd never know I'd had chemotherapy.
It's ground-breaking.
In the U.S., five patients who first had the treatment in trials five years ago are still alive. Our team at Southampton is the first in the UK to perform this technique.

Financial Update

Cash & Cash Equivalents:	**$42.8 million at March 31, 2013**
ATM Program	**up to $50.0 million available**
Committed Equity Financing Facility (CEFF)	**Up to $23.9 million as of March 31, 2013**
Working Capital Line of Credit:	**$20 million credit facility**
Debt:	**None**
Cash Utilization:	**$11.3 million in 1Q 2013** **Projected quarterly cash spend:** **$9-$12 million for first half of 2013** **$9-$10 million for Q3 2013** **$6-$8 million for Q4 2013**
Shares Outstanding:	**96.8 million (107.8 million fully diluted[1,2]) as of March 31, 2013**

1) Fully diluted includes an additional 5.6 million options and 5.4 million warrants
2) Includes 5.6 million shares issued to Terrapin Opportunity L.P. on April 1, 2013

Multiple Capital Resources Available to Execute Plan

Concentrating the Power of Chemotherapy™