UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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 9, 2015

Delcath Systems, Inc. (Exact Name of Registrant Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation)

001-16133 (Commission File Number)

06-1245881 (I.R.S. Employer Identification No.)

1301 Avenue of the Americas, 43rd Floor New York, New York (Address of Principal Executive Offices)

10019 (Zip Code)

Registrant's telephone number, including area code: (212) 489-2100

Not Applicable (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: | | | | | | |
|---|---|--|--|--|--|--|
| |] | 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.

(d) Exhibits.

Exhibit No.

Description of Exhibit

99.1 Delcath Systems, Inc. Investor Presentation Slides

SIGNATURE

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.

Date: October 9, 2015

By: /s/ Jennifer K. Simpson

Jennifer K. Simpson

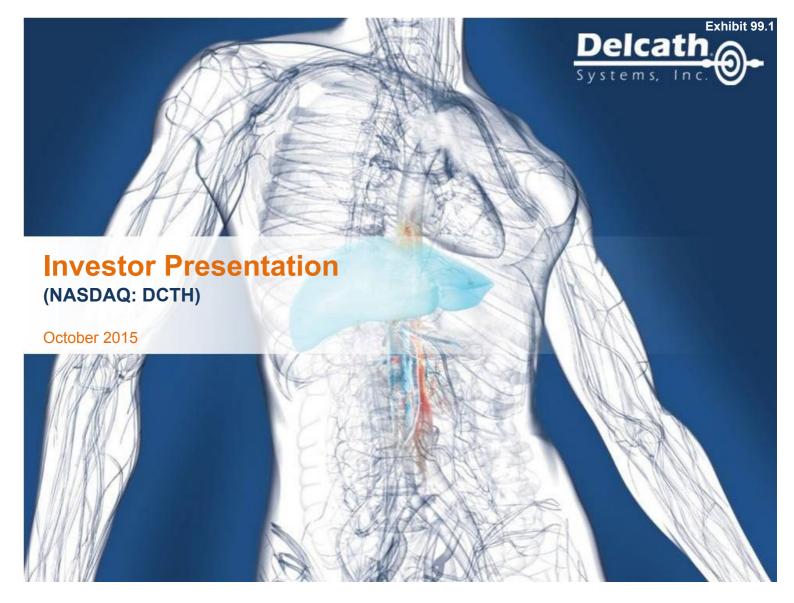
Director, President and Chief Executive Officer

EXHIBIT INDEX

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Forward-looking Statements

This presentation contains forward-looking statements, within the meaning of the federal securities laws, related to future events and future financial performance which include statements about our expectations, beliefs, plans, objectives, intentions, goals, strategies, assumptions and other statements that are not historical facts. Forward-looking statements are subject to known and unknown risks and uncertainties and are based on potentially inaccurate assumptions, which could cause actual results to differ materially from expected results, performance or achievements expressed or implied by statements made herein. Our actual results could differ materially from those anticipated in forward-looking statements for many reasons, including, but not limited to, uncertainties relating to: the timing and results of future clinical trials including without limitation the OM, HCC, ICC, and mCRC trials in the Company's Clinical Development Program, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system in Europe, our ability to obtain reimbursement for the CHEMOSAT system and the impact on sales, if any, of reimbursement in various markets, including without limitation Germany and the United Kingdom, our ability to successfully commercialize the Melphalan/HDS system and the potential of the Melphalan/HDS system as a treatment for patients with primary and metastatic disease in the liver, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter relating to the ocular melanoma indication and the timing of the same, approval of the Melphalan/HDS system by the U.S. FDA, acceptance of the Phase 3 trial publication, the impact of presentations and abstracts at major medical meetings and congresses (SSO, ASCO, CIRSE, ESMO, EADO, RSNA) and future clinical results consistent with the data presented, approval of the current or future Melphalan/HDS system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the U.S. and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same, uncertainties relating to the timing and results of research and development projects, and uncertainties regarding our ability to obtain financial and other resources for any clinical trials, research, development, and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission including the section entitled "Risk Factors" in our most recent Annual Report on Form 10-K and our Reports on Form 10-Q and Form 8-K.

About Delcath Systems

- A specialty pharmaceutical and medical device oncology company with a principal therapeutic focus on the treatment of primary liver cancer and other cancers that have metastasized to the liver
- Proprietary system isolates the liver from circulation, delivers a substantially higher concentration of chemotherapy (melphalan) compared with systemic doses, and filters most of the chemotherapy out of the blood prior to returning it to the patient
- In late-stage clinical development in the U.S. with initial commercial activities underway in Europe
- Initially pursuing orphan indications in metastatic ocular melanoma, hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC)

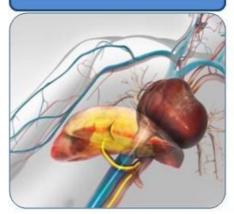
Seeking to Make a Clinically Meaningful Difference For Cancer Patients With Liver Dominant Disease

Our Solution

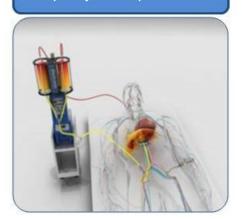
Liver Isolated Via Double Balloon Catheter In IVC



Melphalan Infused Directly Into Liver Via Catheter In Hepatic Artery



Blood Exiting The Liver Filtered By Proprietary Extra-corporeal Filters



- Our proprietary system isolates the liver circulation, delivers a high concentration of chemotherapy (melphalan) and filters most of the chemotherapy out of the blood prior to returning it to the patient
- The procedure typically takes approximately 2-3 hours to complete and involves a team including the interventional radiologist, oncologist, anesthesiologist and perfusionist
- We believe more than 250 treatments with improved device and procedure provide confidence safety can be validated in a controlled setting

Whole Organ-Focus Disease Control

Investment Highlights

- Late-stage asset clinically meaningful efficacy demonstrated in >600 procedures and in multiple tumor types
- Active clinical program initiating global Phase 3 study in ocular melanoma; HCC/ICC Phase 2 program ongoing
- Unique, highly differentiated solution multiple orphan designations create barriers to entry
- Early stage commercialization in EU >250 procedures performed in EU with 2nd Generation product and protocol
- Imminent valuation milestones 2015 value drivers include publications, reimbursement and clinical data
- Attractive business model initial orphan focus and anticipated high gross margins form basis of profitable long-term model
- **Experienced management team –** aligned with requirements of clinically driven pharmaceutical industry

Large, Compelling Market Opportunity

2015 Milestones

1H-2015

- NUB reimbursement decision in Germany Value 4 awarded for 2015
- Submit Phase 3 metastatic melanoma trial results for publication
- EU registry open for enrollment
- ICC cohort open for enrollment

2H-2015

- ✓ ZE Reimbursement in Germany
- EADO Abstracts released
- RSNA Abstract released
- Initiation of global Phase 3 metastatic ocular melanoma program
- Interim evaluation on HCC/ICC program

Executing on Multiple Fronts to Create Value

The Liver: A Life-Limiting Organ

- Cancers of the liver remain a major unmet medical need
 - Large global patient population approximately 1.2 million* patients diagnosed annually with primary or metastatic liver cancer
 - The liver is often the life-limiting organ for cancer patients and one of the leading causes of cancer death
 - Prognosis after liver involvement is poor, with overall survival generally less than 12 months
- CHEMOSAT® Melphalan/HDS is a proprietary product uniquely positioned to potentially treat the entire liver as a standalone or complementary therapy

Effective Liver Cancer Treatment Remains a Major Unmet Medical Need

* SOURCE - 2008 GLOBOCAN

Existing Liver Cancer Treatments Landscape

| Treatment | Advantages | Disadvantages |
|---|--|---|
| Systemic | Non-invasiveRepeatable | Systemic toxicitiesLimited efficacy in liver |
| Regional (e.g., Isolated Hepatic Perfusion) | Therapeutic effectTargeted | Invasive/limited repeatabilityMultiple treatments are required but not possible |
| Focal (e.g., surgery, radioembolization, chemoembolization, radiofrequency ablation) | Partial removal or treatment of tumors | Only 10%-20% are resectable Invasive and/or limited repeatability Treatment is limited by tumor size, number of lesions and location Tumor revascularization Cannot treat diffuse disease |

Existing Liver Cancer Treatments Have Limitations

Melphalan Dosing & Background

| Туре | Dosing (mg/kg) |
|---|----------------|
| Multiple Myeloma (label) | 0.25 |
| Chemoembolization | 0.62 |
| Surgical Isolated Hepatic Perfusion (IHP) | 1.50 |
| Myeloablation | 2.50-3.50 |
| Melphalan/HDS (PHP) | 3.00 |

- Well-understood, dose-dependent, tumor-preferential, alkylating cytotoxic agent that demonstrates little to no hepatic toxicity
- Dose administered directly to liver is substantially higher than that of systemic IV chemotherapy
- Melphalan, an established chemotherapy agent, is proven active at high doses with broad antitumor activity

An Established Drug for Liver Cancer Therapy

Total Available EU & U.S. Market Opportunity

| Cancer Type | Annual Incidence ¹ | Eligible PTS ² | Annual Potential Market Opportunity (Millions) ^{3,5} | Annual Potential Market Opportunity (Millions) ^{4,5} |
|---|----------------------------------|---------------------------|--|--|
| Ocular Melanoma | 5,700-8,600 | 2,600-4,300 | \$104-\$215 | \$208-\$430 |
| Intrahepatic Cholangiocarcinoma (ICC) | 11,500 | 6,500 | \$260-\$330 | \$520-\$660 |
| Hepatocellular Carcinoma (HCC) | 64,500 | 7,600-14,700 | \$304-\$735 | \$608-\$1,470 |
| Colorectal (CRC) | 411,000 | 40,000-55,000 | \$1,600-\$2,750 | \$3,200-\$5,500 |
| Total EU & U.S. | 492,700-495,600 | 56,700-80,500 | \$2,268-\$4,030 | \$4,536-\$8,060 |

Notes:

- 1) Globocan, American Cancer Society
- 2) LEK, Strategy&, Company Estimates
- 3) Assumes average of 2TX/patient
- Assumes average of 4TX/patient
- 5) Assumes \$20,000-\$25,000 USD/TX

Cancers Of The Liver Remain a Multibillion-Dollar Unmet Medical Need

European Commercial Activity



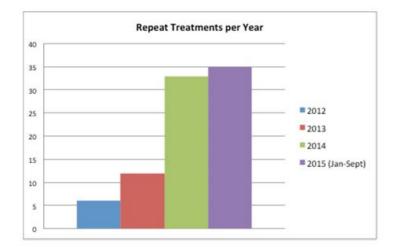
CHEMOSAT® Hepatic Delivery System

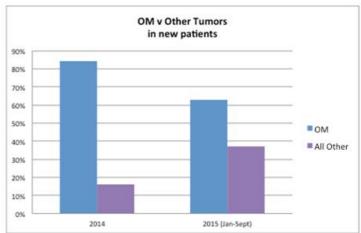
- Approved as Class IIb Medical Device; kit supplied without melphalan
- Broad indication for intra-hepatic administration of melphalan hydrochloride and subsequent filtration of the venous blood return
- >250 commercial procedures performed in leading cancer centers across the EU
- ZE National Procedure Code Established for 2016; 2015 Reimbursement via Individual Funding Requests
- UK private pay insurance; block grants pending
- 2015 YTD EU Sales exceed 2014 on local currency basis

ZE Reimbursement

- First National Reimbursement Coverage Mechanism for CHEMOSAT in Europe
- Establishes DRG Code for CHEMOSAT procedures in Germany
- Augments coverage under established codes until dedicated, comprehensive DRG code can be established
- Hospitals negotiate reimbursement level with insurers beginning Feb 2016
- Replaces annual NUB process
- ZE Coverage in response to applications submitted by German Radiology Society;
 represents significant support for CHEMOSAT TX for cancers in the liver

Increasing & Expanding Clinical Utilization





All other includes: cutaneous melanoma, HCC, ICC, CRC, breast mets, neuroendocrine mets, pancreatic, mucosal melanoma, sarcoma, and gastric mets

Utilization Expanding Into Other Tumor Types Beyond Ocular Melanoma

Clinically Differentiated Results

- Phase 1, 2 and 3 trials produced positive results in multiple histologies
- Melanoma Liver Mets
 - o Positive Phase 3 results in hepatic metastatic melanoma
 - o n=93 (90% ocular melanoma, 10% cutaneous melanoma)
- Neuroendocrine Tumor (NET) Liver Mets
 - mNET cohort in Phase 2 trial showed encouraging 42% objective response rate (ORR) vs. ~10% for approved targeted therapy
 - Median overall survival of ~32 months on ITT basis
- Hepatocellular Carcinoma (HCC)
 - Positive signal with high-dose melphalan in HCC cohort of Phase 2 trial (5/8 patients) is encouraging when approved systemic therapies have modest efficacy and challenges with tolerability
- Colorectal Cancer (CRC) Liver Mets
 - Data from surgical Isolated Hepatic Perfusion (IHP) with melphalan indicates strong potential in well-defined patient population with earlier stage CRC yielding ~50-60% median response rate and median OS of 17.4-24.8 mos

Encouraging Initial Results on a Broad Range of Histologies

Clinical Development Program

| Trials | Tumor | Objectives | | |
|------------------------|---|---|--|--|
| Phase 3 Pivotal Trial | OM liver mets | Global Phase3 trial to start 2H-2015 ~240 PTS, 30 mos accrual, 2017 Interim Analysis Primary endpoint: OveralBurvival (OS) Believed to be fastest pathway to NDA approval in the U.S. | | |
| | HCC (unresectable confined to the liver) | Protocol 201 (U.S. only) Safety, efficacy of Melphalan/HDStreatment followed by sorafenib Evaluate ORR (mRECIST) Assess safety, PFS Characterize systemic exposure of melphalan Assess patient QoL | | |
| Phase 2 Program | | Protocol 202 (EU only) Safety,efficacy of Melphalan/HDS <u>treatment w/o sorafenib</u> in patients with unresectable liver cancer Evaluate ORR (mRECIST) Assess safety, PFS Characterize systemic exposure of melphalan Assess patient QoL | | |
| | ICC (unresectable confined to the liver) | Added to 202 HCC trial protocol ORR of Melphalan/HDS treatment in patients with intra-hepatic cholangiocarcinoma (ICC) Other measures as specified in the 202 EU protocol Signal-seeking go/no-go decision 2H-2015 | | |
| Investigator Initiated | mCRC | University ofLeiden study; 10 patientsreated to date | | |
| Trials | HCC | Johannes Wolfgang Goethe Universityospital (Frankfurt) study; different patient selection from 202 study; open for enrollment | | |
| EU Commercial Registry | EU Commercial Cases | Openfor enrollment; data collection on safety, QoLassessments Potential efficacy signals in additional tumor types Support reimbursement in key markets | | |

OM Metastases Rationale

- OM has high incidence of liver metastases
 - Up to 90% of patients with metastases will have liver involvement
 - Life expectancy of approximately 6 months
 - 5,700 8,600 cases of OM liver metastases diagnosed in U.S. and EU annually
- Clear efficacy signal seen in prior Phase 3 trial of Melphalan/HDS
- · Currently no standard of care
- Believed to be fastest pathway to NDA approval in the U.S.
- FDA granted Melphalan/HDS orphan drug designation for treatment of OM

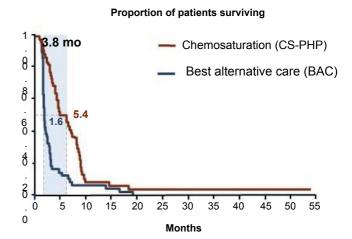
Proven Efficacy in Attractive Orphan Opportunity

*Sources: ACS, SEER, NIH, OMF, KOL Interviews, 2014 3 rd Party Analysis

Previous Ocular Melanoma Mets Phase 3 Results

Hepatic Progression Free Survival (hPFS)

Overall Progression Free Survival (Investigator)



Intent-to-Treat Analysis (June 2012)

5.3 mos improvement in hPFS All were recipients

- Hazard ratio = 0.50
- (95% CI 0.31–0.80)
- p=0.0029

4 subjects remain alive at 5-8 years All were recipients of CS-PHP

Intent-to-Treat Analysis (June 2012)

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

Clinically Meaningful Benefit Previously Demonstrated for Metastatic OM Patients

HCC & ICC Rationale

- Significant opportunity in the U.S. and EU
 - o HCC most common primary cancer of the liver
 - ~76,000* cases diagnosed annually
 - ICC represents ~15% of new HCC cases diagnosed annually
 - ~90% HCC/ICC PTS not candidates for surgical resection
 - o 20-30% PTS candidates for focal interventions
- Large unmet medical need in first-line therapy
 - Only one approved systemic therapy for HCC in the U.S., EU and certain Asian markets
- FDA granted Melphalan/HDS orphan drug designations for treatment of unresectable HCC & ICC
- Efficacy signals from early commercial uses in EU

Large, Deadly Disease in Need of Better Treatments

*Sources: WHO, KOL Interviews, 20143 rd Party Analysis

Prior FDA Experience

- New Drug Application (NDA) submitted August 2012 seeking indication in OM liver metastases with first-generation filter and procedure
- ODAC meeting in May 2013
 - Efficacy shown with statistical significance
 - Negative vote due to benefit/risk analysis
 - Complete FDA & Delcath ODAC briefing materials available at www.delcath.com/clinical-research/clinical-bibliography/
- Complete Response Letter (CRL) issued September 2013
- FDA requests include, but not limited to:
 - Well-controlled randomized trial(s) to establish the safety and efficacy using the to-be-marketed device configuration
 - Overall survival as the primary efficacy outcome measure
 - Demonstrate clinical benefits outweigh risks

FDA Learnings Provide Beneficial Clinical Study Roadmap

Risks Observed in Previous Clinical Program

- Risks observed with prior product and procedure protocol
- Integrated safety population of patients showed risks associated with melphalan/HDS included:
 - 4.1% incidence of death due to adverse reactions
 - 4% incidence of stroke
 - 2% reported incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment
 - ≥ 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
- Safety improvements implemented

Treating Physicians in U.S. and EU Report Improved Safety Profile

Growing Body of Clinical Support for CHEMOSAT







- ≤4 TX being administered; shown to be safe and well tolerated
- o Providing clinical benefit and good QoL
- Reimbursement continues to be covered through individual funding requests











Abstracts Accepted at Major Medical Meetings

- o ESSO 2014
- o SSO 2015
- o ASCO 2015
- o CIRSE 2015
- o EADO 2015
- o ESMO 2015
- o RSNA 2015

Recent Data Presentations – ECCO 2015



Leiden University Medical Center, Erasmus Medical Center (the Netherlands)

Treating Unresectable Liver Metastases of Uveal Melanoma with (Percutaneous)

Isolated Hepatic Perfusion with Melphalan: Results from Two Experienced Centers

- Investigators compared TX with IHP and PHP for ocular melanoma liver metastases
- IHP cohort (n=30) treated between 1999 and 2009
 - o PFS was 6 mos
 - Disease recurrence mainly in the liver
 - o OS was 10 mos (vs 6 mos historic avg for IHP)
- PHP cohort (n=9); PTS received 15 PHP TX since Feb 2014
 - Max follow up period was 14 mos
 - o 8 PTS still alive, 7 without disease progression
 - Decrease in red/white blood cell count observed following TX; 3 PTS received blood transfusion
 - o TX overall was well tolerated
- Conclusion: PHP appears to be effective/safe procedure in select patients with unresectable liver metastases from CRC or OM and can be repeated

Recent Data Presentations – CIRSE 2015

Leiden University Medical Center (the Netherlands)

Safety and efficacy of Delcath 2nd Generation filter in PHP with melphalan for unresectable hepatic metastases of colorectal cancer and uveal melanoma

 15 PHP procedures performed with CHEMOSAT on 10 pts; PK blood samples @ baseline, set intervals

C RSE

- PHP performed with melphalan dose of 3mg/kg; 1st blood sample filtration efficiency = 93%
- Grade 3 complications (mostly leukocytopenia, thrombocytopenia) in 7 pts; febrile neutropenia (w/bacterial pharyngitis) in 1 pts (not seen following introduction of growth factors)
- Conclusion: 2nd Generation filter efficiency very high; PHP associated with no mortality and acceptable morbidity

Southampton University (United Kingdom)

Lessons and Early Results from the Largest Single Center Experience in Europe of Treating Ocular Melanoma Liver Metastases with Chemosaturation via Percutaneous Hepatic Perfusion

- Retrospective analysis of 22 pts; 20 received TX w/PHP
- 11 pts alive after median 280 days; one complete response > 1yr post TX
- 9 deaths from disease progress after median 264 days post TX
- Complete response in liver in 2 pts (10%), 13 pts (65%) had partial liver response, 2 pts (10%) had stable disease > 3mos
- Conclusion: PHP effective palliative TX in bleak disease with an acceptable side-effect profile

Recent Data Presentations - ASCO 2015



Southampton University Hospital (UK)

- Analysis of 20 ocular melanoma patients who received 34 TX
- Eleven patients remain alive after a median of 280 days with one complete response ongoing at >1 year
- From the diagnosis of liver metastases, 11 patients (55%) survived to one year and 3 (15%) for >2 years; no procedure related deaths were seen
- ORR 85%: 2 patients (10%) demonstrated stable disease for >3 months, 13 patients (65%) had a partial response, 2 patients (10%) demonstrated complete response
- Nine deaths from disease progression occurred after a median of 264 days from the first procedure

Adverse Events

- Early AEs often expected with percutaneous hepatic perfusion (PHP) were observed including coagulopathy, electrolyte disturbances and transient transaminases (elevated liver enzymes). Rare late AEs (1 patient each) included hair loss, skin rash, myelosuppression and persistent transaminases (elevated liver enzymes)
- AEs seen were grade 1 (n=12), 2 (n=13), 3 (n=5) and 4 (n=1)
- o Grade 4 complication was pulmonary edema due to fluid overload

Recent Data Presentations - SSO 2015



Moffitt Cancer Center (Tampa, FL)

Hepatic Progression Free and Overall Survival after Regional Therapy to the Liver for Metastatic Melanoma

- Retrospective analysis of 30 patients with ocular or cutaneous melanoma treated with Melphalan/HDS (n=10), chemoembolization (CE, n=12), and yttrium-90 (Y90, n=6)
- Study showed significant difference in hepatic progression free survival (HPFS) for Melphalan/HDS (310 days), CE (80 days), Y90 (54 days)
- Median overall survival (OS) longest for Melphalan/HDS (736 days) vs Y90 (285 days) CE (265 days), but did not reach statistical significance
- Authors concluded that HPFS and progression free survival (PFS) were significantly prolonged with Melphalan/HDS vs CE and Y90

Coming Soon



Leiden University Medical Center in the Netherlands

Treating Unresectable Liver Metastases Of Uveal Melanoma With

Percutaneous Hepatic Perfusion With Melphalan

Southampton University in the United Kingdom

Liver Directed Treatment Of Metastatic Uveal Melanoma By

Chemosaturation Via Percutaneous Hepatic Perfusion – A Single Centre

Experience



Frankfurt University Hospital

Chemosaturation with Percutaneous Hepatic Perfusion of Melphalan for Hepatic Metastases from Uveal Melanoma: Multiinstitutional Evaluation

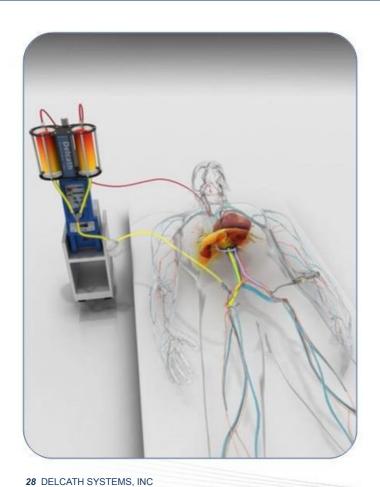
Cash & Capital Resources

| Cash & Cash Equivalents | \$19.1 million at July 31, 2015 | | |
|--------------------------|--|--|--|
| Debt | None | | |
| ATM Program ¹ | \$40 million available at July 31, 2015 | | |
| Shares Outstanding | 21.8 million (40.7 million fully diluted ²) at July 31, 2015 | | |

- Subject to market conditions and certain limitations
 Fully diluted includes approximately 0.8 million options and 18.1 million warrants

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

In Summary



- Attractive multi-billion dollar orphan drug business model
- Unique, highly differentiated solution
- Late-stage asset in U.S. with active clinical development program
- Early commercial activity in EU with increasing sales/procedure volumes
- Compelling emerging data
- Imminent valuation milestones
- Experienced pharmaceutical management team executing a data-driven plan

