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): January 22, 2016

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

Delaware	**001-16133**	**06-1245881**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

1301 Avenue of the Americas, 43rd Floor New York, New York	**10019**
(Address of Principal Executive Offices)	**(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: January 22, 2016

By: /s/ Jennifer K. Simpson
Jennifer K. Simpson
Director, President and Chief Executive Officer

EXHIBIT INDEX

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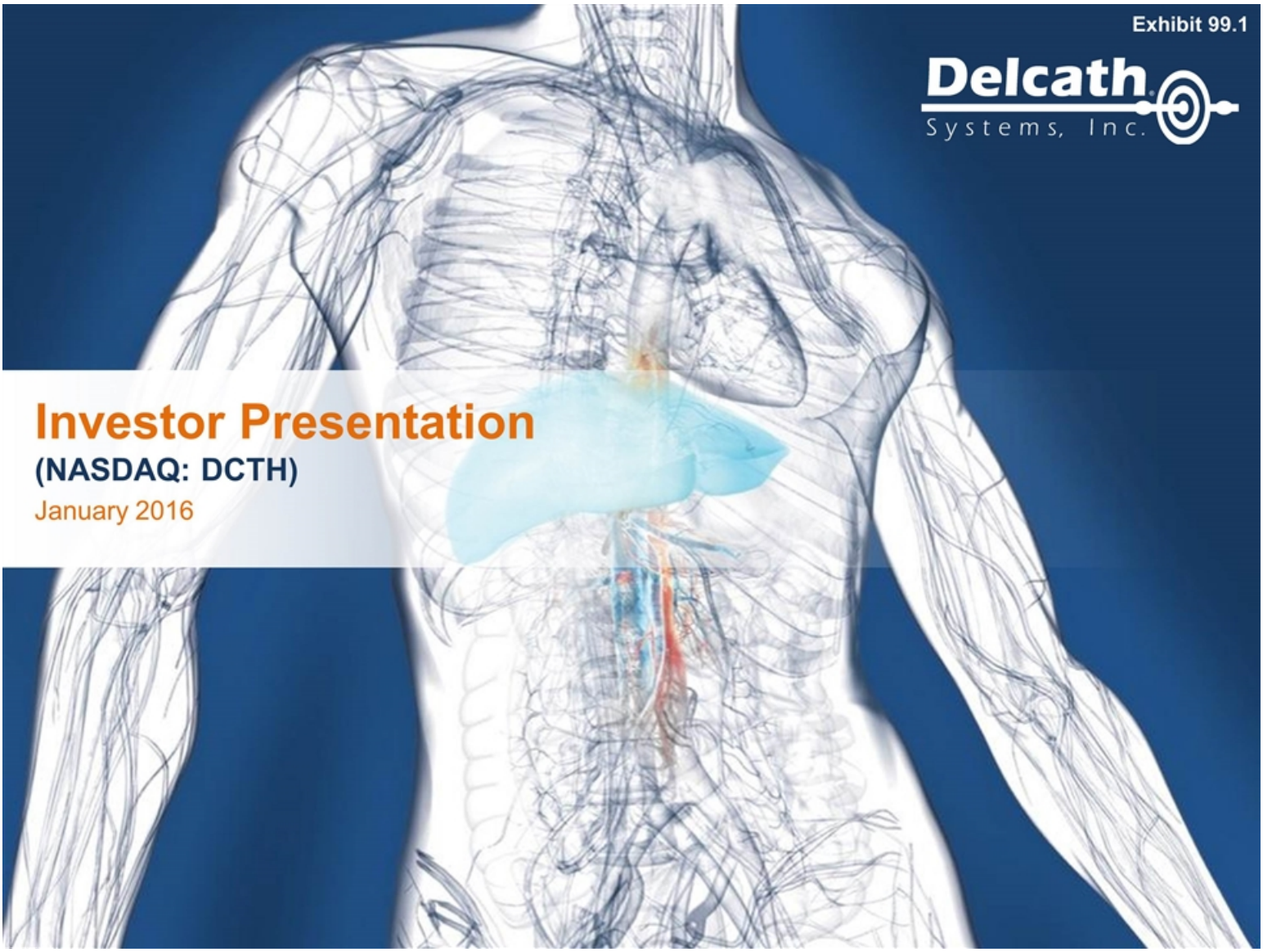
Exhibit 99.1



Investor Presentation

(NASDAQ: DCTH)

January 2016

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 in various markets, including without limitation Germany and the United Kingdom and the impact on sales, if any, of reimbursement in these markets including ZE reimbursement in the German market, 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.

Delcath Systems

- Seeking to make a clinically meaningful difference for patients with cancers of the liver
- Focused on treatment of primary/metastatic liver cancers
- Proprietary system delivers high-dose chemotherapy (melphalan) directly to the liver with extra-corporeal filtration to limit systemic toxicity
- Late-stage clinical development in the US
- Currently Commercial Stage in the EU
- Pursuing orphan indications in metastatic ocular melanoma (OM), hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC)

Value Drivers – Near Term Milestones

2H 2015

- Reimbursement in Germany Awarded for 2016
- Prior P3 Results Published

1H 2016

- FDA SPA Approval
- FOCUS Trial Initiation
- Interim HCC/ICC Data
- EU Registry Data Readout #1

2H 2016

- German ZE Reimbursement Level Defined
- P2 HCC/ICC Enrollment Completed
- EU Registry Data Readout #2
- IIT Data Presentation

Cancers of the Liver - A Major Unmet Medical Need

- Large global patient population of ~1.2 million* patients diagnosed annually with primary or metastatic liver cancer
- Liver a common site of metastases and often the life-limiting organ for cancer patients
- Prognosis is poor, OS generally <12 months
- Currently available/emerging therapies limited

* SOURCE – 2008 GLOBOCAN

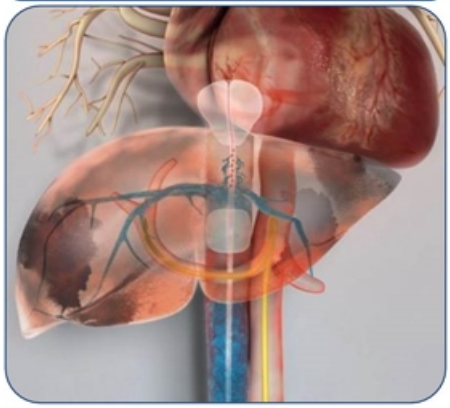
Limitations of Current Liver Cancer Treatments

	Systemic Chemotherapy	Regional Therapy	Surgical Resection	Focal Interventions	Emerging Therapy
	Temozolomide, carboplatin/ Paclitaxel	Isolated Hepatic Perfusion		Y-90, Chemo/ Radiofrequency Ablation	Checkpoint Inhibitors, Immunotherapy
Systemic Toxicities	✔				✔
Limited efficacy in liver	✔				✔
Invasive		✔	✔	✔	
Not Repeatable		✔	✔		
Small % of PTS are candidates		✔	✔		
Limited Efficacy in Diffuse Disease				✔	

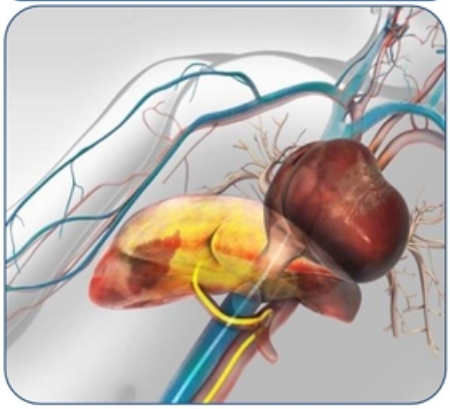
Our Solution – Liver Focused Disease Control

- CHEMOSAT® Melphalan/HDS product uniquely positioned to treat the entire liver as a standalone or complementary therapy
- System isolates the liver circulation, delivers a high concentration of chemotherapy (melphalan), filters most chemotherapy out of the blood prior to returning it to the patient
- Repeatable procedure typically takes ~2-3 hours

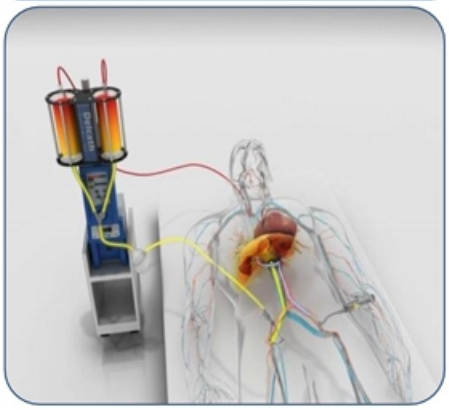
Liver Isolated Via Double Balloon Catheter In IVC



Melphalan Infused Directly Into Liver Via Catheter In Hepatic Artery



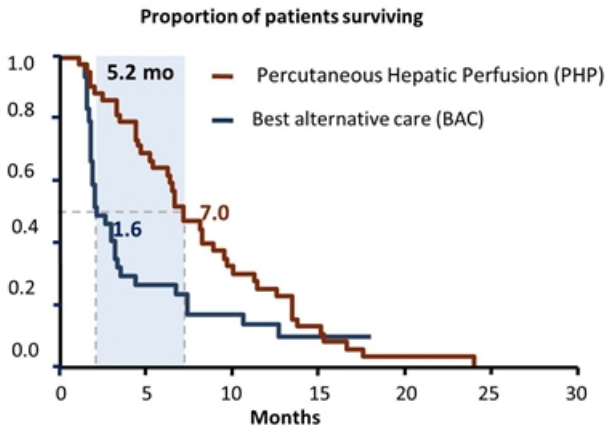
Blood Exiting The Liver Filtered By Proprietary Extra-corporeal Filters



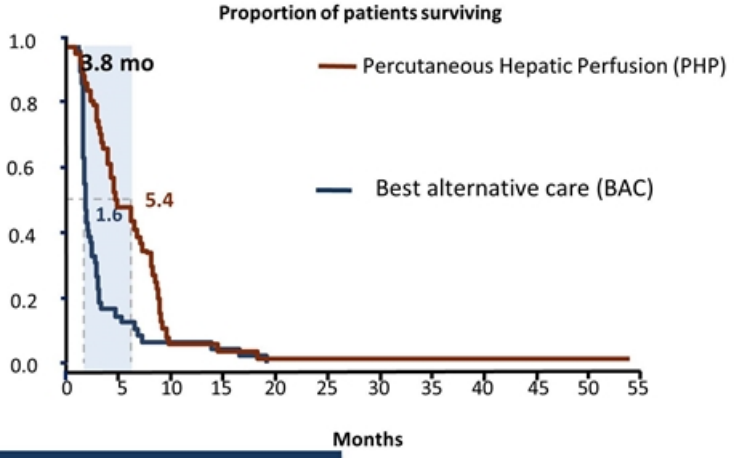
Benefits Demonstrated in Prior Phase 3 Trial

Results of a Randomized Controlled Multicenter Phase 3 Trial of PHP vs. Best Available Care for Patients with Melanoma Liver Metastases – Annals of Oncology 2015

Hepatic Progression Free Survival (IRC Assessment)



Overall Progression Free Survival (INV Assessment)



Intent to Treat Analysis		
n=93 (44 PHP, 49 BAC)	hPFS	PFS
Improvement	5.3 mos	3.8 mos
Hazard Ratio	.50	.42
Confidence	95%, 0.31-0.80	95%, 0.27-0.64
P Value	=0.0029	<0.0001

4 PTS alive as of Dec 2015
All were recipients of melphalan

Multi-Billion Dollar Opportunity in Orphan Indications

Fastest Path to US Market Approval

EU & US TAM			
Cancer Type	Annual Incidence[1]	Eligible PTS[2]	Annual Potential Market Opportunity (Millions)[3,4]
Ocular Melanoma	**5,700-8,600**	**2,600-4,300**	**~$104-$430**
Intrahepatic Cholangiocarcinoma (ICC)	11,500	6,500	~$260-$660
Hepatocellular Carcinoma (HCC)	64,500	7,600-14,700	~$304-$1,470
Colorectal (CRC)	411,000	40,000-55,000	~$1,600-$5,500
Total EU & U.S.	**492,700-495,600**	**56,700-80,500**	**~$2,268--$8,060**

Notes:
1) Globocan, American Cancer Society
2) LEK, Strategy&, Company Estimates
3) Assumes 2-4TX/patient
4) Assumes ~$20,000-$25,000 USD/TX

Clinical Development Program

Tumor Type	Program	IIT	P2	P3	Upcoming Milestones
Ocular Melanoma (OM)	FOCUS Trial P3 Pivotal Study in Hepatic Dominant OM			◆	• SPA Agreement • Trial Initiation • 1st PTS Treated
Hepatocellular Carcinoma (HCC)	202 HCC/ICC Trial (EU Only)		◆		• Interim Efficacy/Safety Data
Intrahepatic Cholangiocarcinoma (ICC)	201 HCC/ICC Trial (US Only)		◆		
Other	Select Investigator Trials in HCC/CRC	◆			• Presentation of INV Data
Multi-Histology	Prospective Commercial Registry (EU Only)	N/A			• Data on 1st 20 PTS

IIT=Investigator Initiated Trials
P2= Phase 2
P3= Phase 3

Initial EU Commercialization

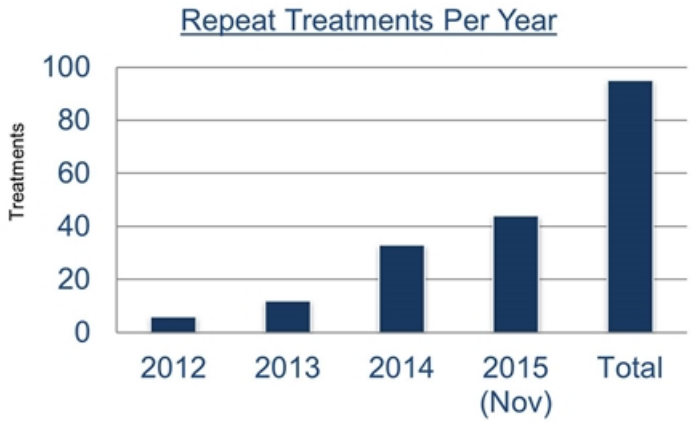
CHEMOSAT®

- CE Marked as Class IIb Medical Device with broad indication
- ~230 commercial procedures performed on ~140 patients
- Broad range of tumor types treated
- National reimbursement established in Germany for 2016 after <3 years of commercial activity
- Prospective Registry activated in 2015
- FY'15 Sales (through Q3) exceed FY'14 FY Sales by ~83% w/o reimbursement

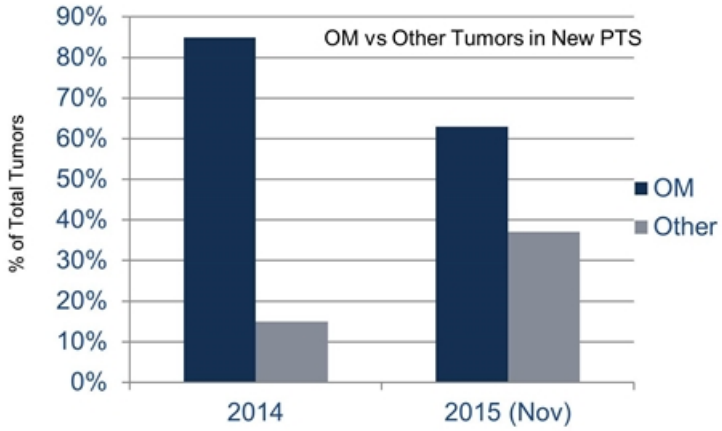
CHEMOSAT Available At Over 20 Major Cancer Centers In 7 EU Countries

Growing & Expanding Clinical Utilization

- EU clinical adoption increasing
- Physicians opting to retreat patients as familiarity/confidence grows
- Data from EU experience presented at multiple medical conferences in 2015



- Usage expanding beyond initial use in metastatic OM
- Usage includes PTS with CM, HCC, ICC, CRC, breast mets, NET mets, pancreatic, mucosal melanoma, sarcoma, and gastric mets



2015 Data Presentations

Abstract	N=	Efficacy					Toxicity/AEs	Notes
		OS	CR	PR	SD	HPFS		
Zager – SSO	30 (CM, OM)	736 days				310 days		OS results provide confidence for new P3 Trial
Southampton - ASCO	20		2	13	2		GR1 (n=12), GR2 (n=13), GR3(n=5) GR4(n=1)	11 pts alive median 280 days, 1 CR ongoing >1yr
LUMC - CIRSE	10	Study analyzed filtration efficiency & TX tolerability					GR3(n=7)	Filtration efficiency =93%
Southampton - CIRSE	22		2	13	2			11 pts alive median 280 days; 1 CR >1yr post TX
Leiden, Erasmus – ECCO/ESMO	9	8 PTS still alive, 7 w/o disease progression					Decrease red/white BC count; 3 PTS rec'd blood TF	TX overall well tolerated
Southampton -EADO	20		1	4	11	181 days (@ cut off)	Non-hemo AE's n=3 GR2(89%), GR3 (n=4), GR2-4 neutropenia (n=4)	TX can be used safely by exp team; high PFS and OS in select OM pts
Leiden - EADO	20 (CRC, OM)	10 PTS remain in FU, 4 w/o progression; Max FU=					GR 3,4 n=4	TX appears safe/effective in select OM PTS
Frankfurt - EADO	14			4	5		7 leukopenia, 6 thrombocytopenia, 2 neutropenia	11 of 14 PTS evaluable; TX potential demonstrated

CM=cutaneous Melanoma, OM=Ocular Melanoma, CRC=Colorectal Cancer

Cash & Capital Resources

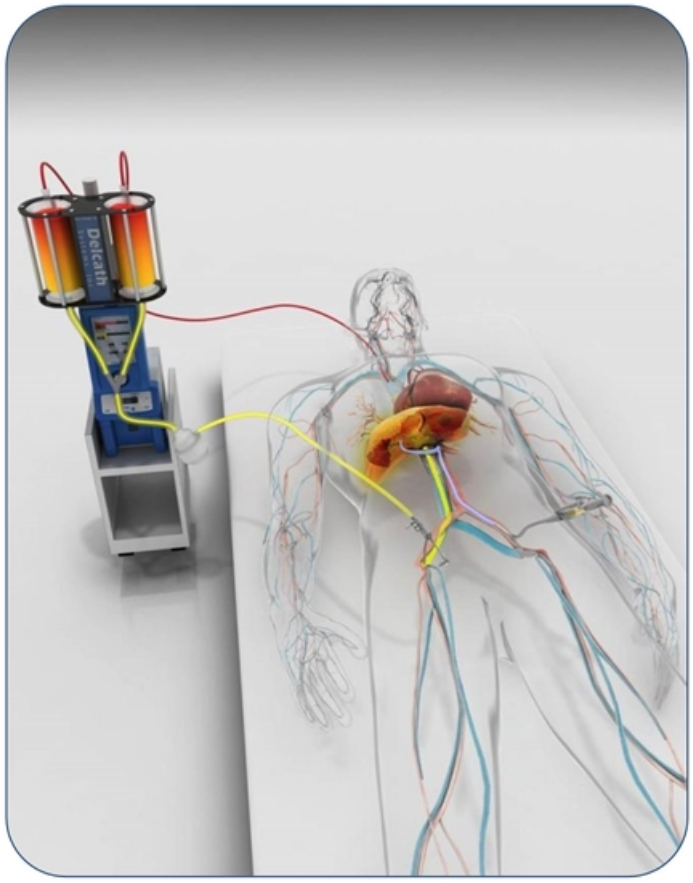
Cash & Cash Equivalents	$16.7 million at Sept 30, 2015
Debt	None
ATM Program[1]	$40 million available at Sept 30, 2015
Shares Outstanding	21.8 million (41.3 million fully diluted[2]) at Sept 30, 2015

1) Subject to market conditions and certain limitations
2) Fully diluted includes approximately 0.8 million options, 0.6 million in unvested restricted shares and 18.1 million warrants

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

Investment Highlights

- Attractive multi-billion dollar orphan drug business model
- Unique, highly differentiated solution
- Late-stage asset in US with active clinical development program
- Early commercial activity in EU with increasing sales/procedure volumes
- Imminent valuation drivers
  - FDA SPA Agreement
  - P3 Trial Initiation
  - 2016 German Reimbursement



Concentrating the Power of Chemotherapy™

Appendix

Hepatic Progression Free and Overall Survival after Regional Therapy to the Liver for Metastatic Melanoma - Moffitt Cancer Center (Tampa, FL)

- **Methods –**
  - 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)
- **Results -**
  - 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
- **Conclusion** - Authors concluded that HPFS and progression free survival (PFS) were significantly prolonged with Melphalan/HDS vs CE and Y90

ASCO
American Society of Clinical Oncology

Single Centre Experience of Chemosaturation Percutaneous Hepatic Perfusion in the Treatment of Metastatic Uveal Melanoma - Southampton University Hospital (UK)

- **Methods -** Analysis of 20 ocular melanoma patients who received 34 TX
- **Results -**
  - 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)
  - Grade 4 complication was pulmonary edema due to fluid overload
- **Conclusion -** results show that PHP (CHEMOSAT) can be used safely to control hepatic metastases in selected UM patients with a high rate of hepatic progression free and excellent overall survival

Safety and efficacy of Delcath 2nd Generation filter in PHP with melphalan for unresectable hepatic metastases of colorectal cancer and uveal melanoma - Leiden University Medical Center (the Netherlands)

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

Lessons and Early Results from the Largest Single Center Experience in Europe of Treating Ocular Melanoma Liver Metastases with Chemosaturation via Percutaneous Hepatic Perfusion - Southampton University (United Kingdom)

- 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**

Treating Unresectable Liver Metastases of Uveal Melanoma with (Percutaneous) Isolated Hepatic Perfusion with Melphalan: Results from Two Experienced Centers - Leiden University Medical Center, Erasmus Medical Center (the Netherlands)

- **Methods -** Investigators compared TX with IHP and PHP for ocular melanoma liver metastases
- **Results -**
  - IHP cohort (n=30) treated between 1999 and 2009
    - PFS was 6 mos
    - Disease recurrence mainly in the liver
    - 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
    - 8 PTS still alive, 7 without disease progression
    - Decrease in red/white blood cell count observed following TX; 3 PTS received blood transfusion
    - 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**

Liver Directed Treatment Of Metastatic Uveal Melanoma By Chemosaturation Via Percutaneous Hepatic Perfusion – A Single Centre Experience Southampton University (United Kingdom)

- **Methods** – A retrospective evaluation of 20 patients treated with CHEMOSAT over 3 years; analysis of survival, tumor response, time to progression and treatment related adverse events; 18 patients able to receive treatment, 17 were evaluable
- **Results** - 10 patients remained alive after median 256 days
  - 1 complete response (6%), 4 partial responses (24%), 11 (65%) stable disease >90 days
  - Progression free survival for patients who had progressed was 181 days at the time of data cut off
  - 6 patients alive >1 year following their first treatment
  - 8 deaths from disease progression occurred median 241 days following first treatment; no treatment related deaths
- **Adverse Events** (AEs) - treatment overall was well tolerated
  - Non-hematological AEs were rare (3)
  - Most common adverse events was transient, mild grade 2 transaminitis and thrombocytopenia (89%); grade 3 anemia seen in 4 patients, grade 2-4 neutropenia was seen in 4 patients
- **Conclusion** - CHEMOSAT can be used safely by experience team to deliver liver directed therapy in selected uveal melanoma patients with high progression free and excellent overall survival

Treating Unresectable Liver Metastases Of Uveal Melanoma With Percutaneous Hepatic Perfusion With Melphalan, Leiden University Medical Center, Erasmus Cancer Institute (the Netherlands) presented by Dr. Mark Burgmans (Leiden)

- **Methods** - two-center Phase 2 study aims to evaluate 20 patients with uveal, or ocular melanoma treated with percutaneous hepatic perfusion (PHP) performed with CHEMOSAT; data from the first 11 patients with a maximum follow up period of 16 months were presented
  - Primary endpoints are response rate (RECIST criteria) following two treatments at 6 week interviews, percentage of patients with stable disease
  - Secondary endpoints are safety, overall survival, hepatic progression free survival, quality of life
- **Results** -18 treatments performed on 11 patients, maximum follow up currently 16 months
  - 10 patients remain in follow up, 4 without progression of disease
- **Adverse Events** - grade 3 or 4 toxicity observed in 4 patients, managed with blood transfusion or platelet infusion
- **Conclusion** - CHEMOSAT appears to be effective and safe procedure in select patients with unresectable liver metastases of uveal melanoma and can be repeated

Chemosaturation with Percutaneous Hepatic Perfusion of Melphalan for Hepatic Metastases from Uveal Melanoma: Multi-institutional Evaluation, poster presented by lead author Prof. Thomas Vogl, Frankfurt University Hospital

- **Methods** - retrospective evaluation of non-resectable hepatic metastases from uveal melanoma treated with CHEMOSAT
  - 14 patients treated 2012-2014; patients received 1-3 treatments
  - 11 PTS evaluated by RECIST criteria; survival time analysis performed, complications registered
- **Results** - 4 (36%) partial response, 5 (46%) stable disease, 2 (18%) progressive disease
  - Survival time ranged from 1. 5 months to 23 months (median OS 6.5 months)
  - Time to progression for two patients who progressed was 6.2 months in one patient; the other died 1.6 months after evaluation
- **Adverse Events** – treatment well tolerated by all 14 patients
  - 7 leukopenia, 6 thrombocytopenia, 2 neutropenia
- **Conclusion -** CHEMOSAT has been manifested as a potential treatment for patient with non-resectable hepatic metastases of uveal melanoma