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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(D)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of report: March 13, 2018**

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**DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-16133**  
(Commission  
File Number)

**06-1245881**  
(IRS Employer  
Identification Number)

**1633 Broadway, Suite 22C, 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)

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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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 7.01 Regulation FD Disclosure**

Delcath Systems, Inc. (the “Company”) is furnishing this Current Report on Form 8-K in connection with the disclosure of information contained in an investor presentation (the “Presentation”) to be used by the Company at various meetings, including on March 13, 2018 at 1:30 PM Pacific Time at the 30th Annual Roth Conference, being held at the Ritz Carlton Hotel, in Dana Point, California from March 11 – 14, 2018. This information may be amended or updated at any time and from time to time through another Current Report on Form 8-K or other means. A copy of the Presentation is furnished herewith as Exhibit 99.1 and is incorporated into this Item 7.01 by reference.

The information furnished in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any registration statement filed pursuant to the Securities Act of 1933, as amended, except as may be expressly set forth by specific reference in such filing.

The Company expressly disclaims any obligation to update or revise any of the information contained in the Presentation.

The Presentation is available on the Company’s investor relations website located at [delcath.com/investors](http://delcath.com/investors), although the Company reserves the right to discontinue that availability at any time.

**Item 8.01 Other Information**

See Item 7.01 above.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

Exhibit 99.1 [Investor Presentation dated March, 2018.](#)

**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: March 13, 2018

By: /s/ Jennifer K. Simpson, Ph.D.

Name: Jennifer K. Simpson, Ph.D.

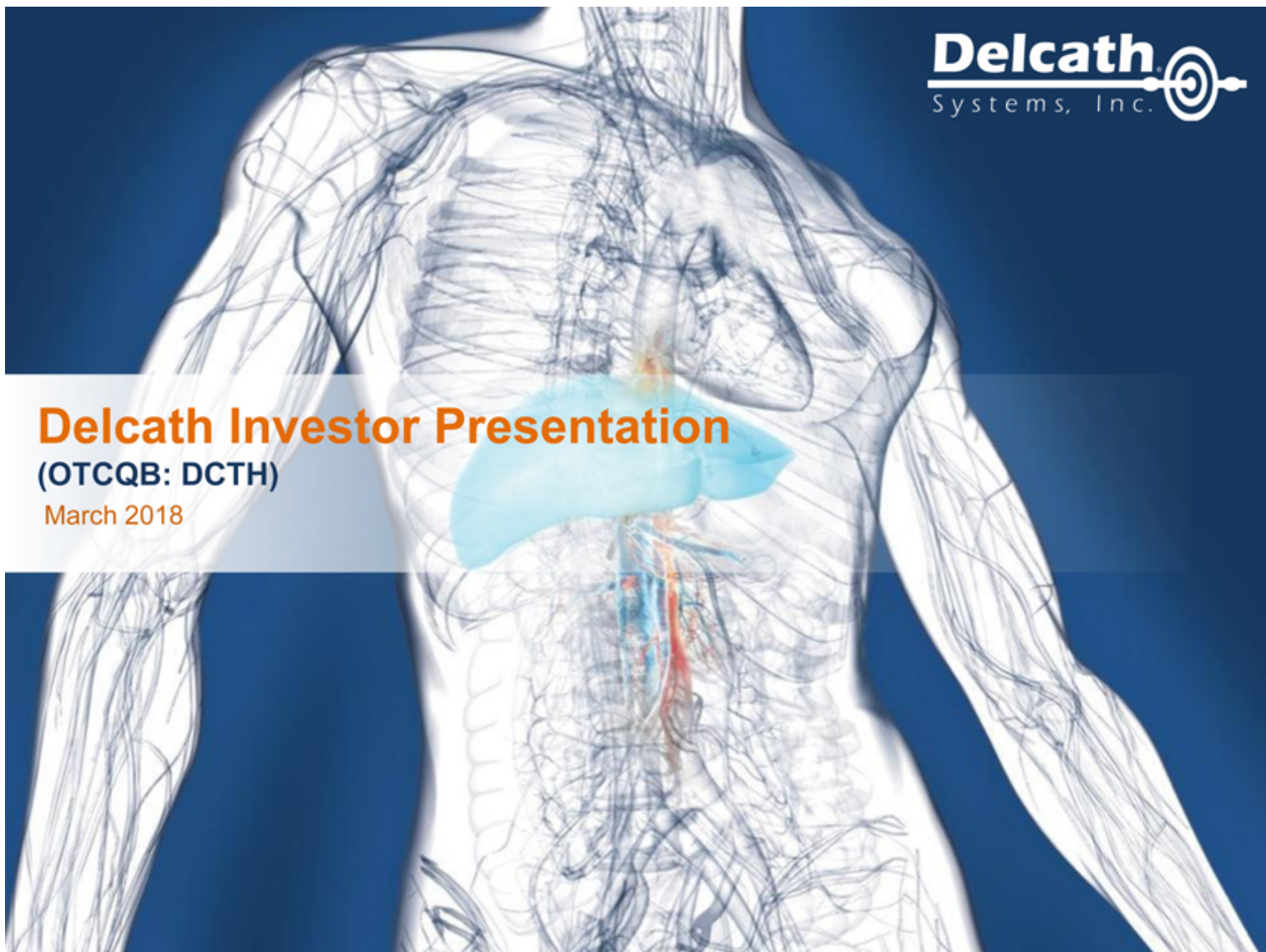
Title: President and Chief Executive Officer



# Delcath Investor Presentation

(OTCQB: DCTH)

March 2018



## 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: our ability to repay and comply with the obligations under our senior secured convertible notes, 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 remaining 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, 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 for year ended December 31, 2016, and our Reports on Form 10-Q for the quarters ended March 30, June 30, and September 30 2017, and all Form 8-K filings made in 2017.



## Delcath Systems

- ◆ Interventional oncology company focused on treatment of primary/metastatic liver cancers
- ◆ Proprietary percutaneous hepatic perfusion (PHP) system delivers high-dose chemotherapy (melphalan) directly to the liver with extra-corporeal filtration to limit systemic toxicity
- ◆ Commercial stage in the EU under the CHEMOSAT® brand
- ◆ Late-stage clinical development in the US (Melphalan/HDS)
- ◆ Pursuit of orphan indications in metastatic ocular melanoma (mOM) and intrahepatic cholangiocarcinoma (ICC)

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**Our Mission is to Make a Clinically Meaningful Difference for Patients with Cancers of the Liver**

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# Clinical / Commercial Pipeline

Program	Phase 2	Phase 3	Registry	Commercialization
HCC	Closed			
ICC	Enrollment Complete	FDA SPA 2017		
mOM		~40 US/EU Centers		
Multi-Histology			EU (Safety, Efficacy QoL)	
Market Approval				EU CE Mark

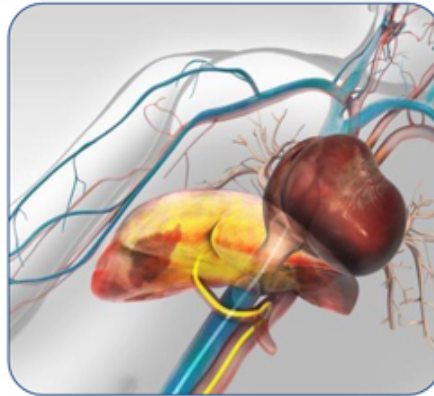
## Our Solution – Liver Focused Disease Control

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

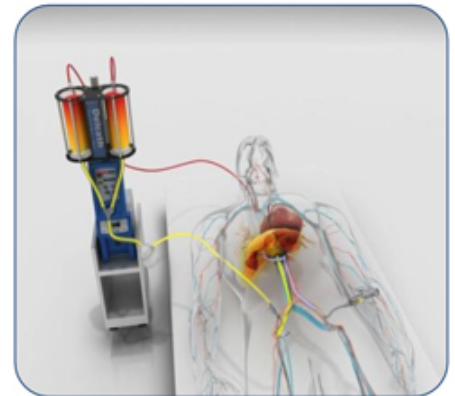
Liver Isolated Via Double Balloon Catheter In IVC



Melphalan Infused Directly Into Liver Via Catheter In Hepatic Artery



Blood Exiting The Liver Filtered By Proprietary Extra-corporeal Filters





## 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, overall survival (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				✓	

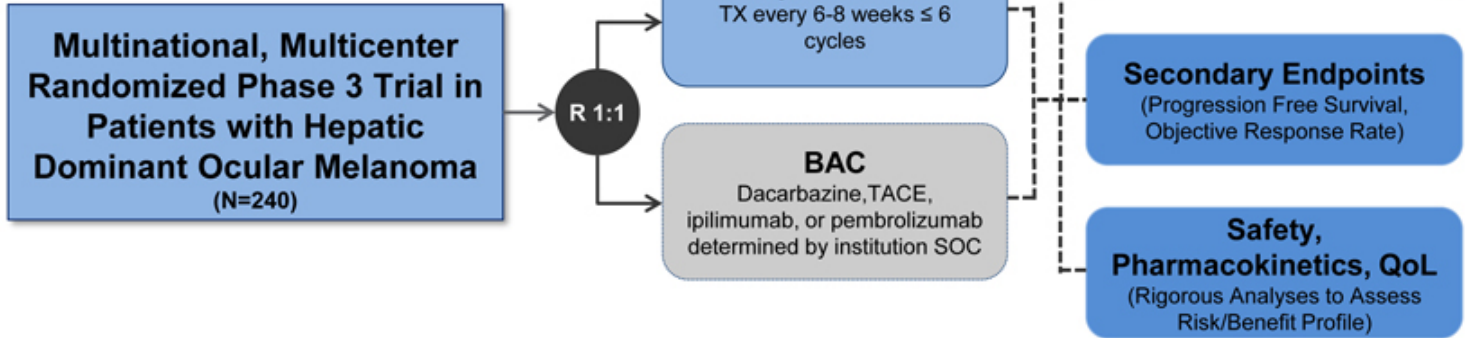
# Building Shareholder Value Through Clinical Development

Tumor Type	Program	Notes	Milestones
Ocular Melanoma (OM)	FOCUS Trial P3 Pivotal Study in Hepatic Dominant OM	<ul style="list-style-type: none"> <li>• Fastest Path to U.S. Market Approval</li> <li>• Amended SPA Jan 2018</li> </ul>	<ul style="list-style-type: none"> <li>✓ Interim Safety Analysis end 2017</li> <li>• Rollout of expanded protocol</li> </ul>
Intrahepatic Cholangiocarcinoma (ICC)	Pivotal Trial in ICC	<ul style="list-style-type: none"> <li>• FDA SPA 2017</li> <li>• Strong Signal in Commercial Setting</li> <li>• Value Driver</li> </ul>	<ul style="list-style-type: none"> <li>• Enrollment to open in 1H 2018</li> </ul>
Hepatocellular Carcinoma (HCC)	201 HCC Trial (US Only)	ICC Cohort Fully Enrolled	<ul style="list-style-type: none"> <li>• ICC Data Release By Investigators</li> </ul>
	202 HCC/ICC Trial (EU Only)	HCC Remains Closed to Enrollment	

# Global Phase III Clinical Trial

## FOCUS

Clinical Trial For Patients with  
Hepatic-Dominant Ocular Melanoma



- ◆ ~40 leading cancer centers in US & EU participating in Phase 3 OM Trial

## Challenges

- ◆ Lack of cross over in the trial design combined with commercial availability of CHEMOSAT in EU inhibiting enrollment
- ◆ Inclusion/exclusion criteria focused on limited extra-hepatic metastases, narrowing available patient pool

## Path Forward

- ◆ Amended SPA with FDA (Jan 2018) expands inclusion/exclusion criteria
- ◆ Expanded number of sites in both EU & US
- ◆ Rollout expanded inclusion/exclusion protocol to participating centers
  - ◆ Updated enrollment projections 2H 2018
- ◆ Awareness campaign

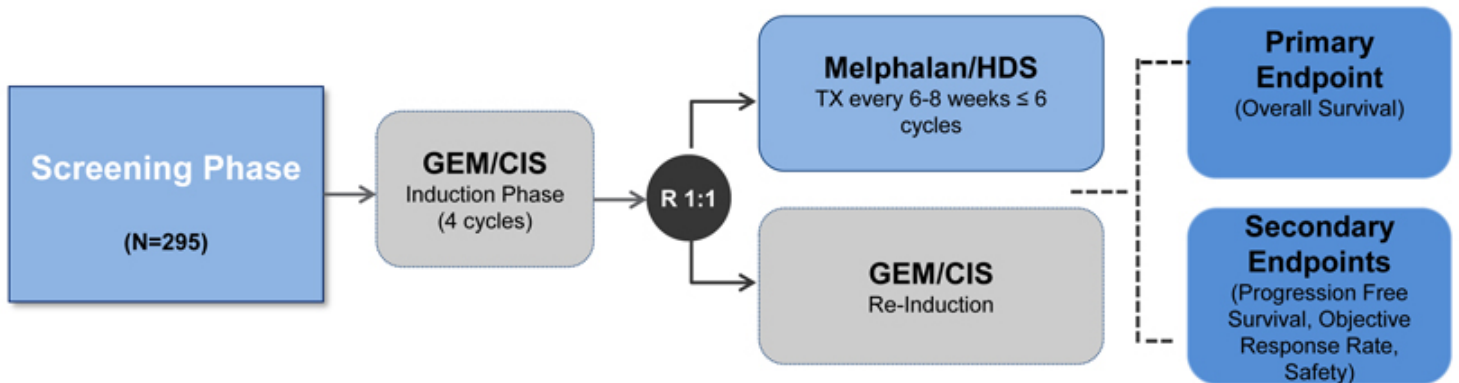
## ICC Development Path

- ◆ Phase 2 ICC Cohort initiated to determine efficacy signal
  - ◆ Patient treatment and data collection continuing; interim data to be released upon maturity
- ◆ Concurrently a multi-center retrospective data collection by EU investigators was conducted in 2015 and determined efficacy signal prior to completion of the ICC cohort
  - ◆ Promising outcomes and observations obtained by EU investigators;
  - ◆ Data were presented at Delcath-sponsored Medical Advisory Panel in 2016;
  - ◆ KOL agreement that ***“CHEMOSAT treatment does, indeed, demonstrate an efficacy signal in ICC and is worthy of full clinical investigation”***
  - ◆ Summary of EU Investigator findings presented at Cholangiocarcinoma Foundation annual meeting in early 2017
  - ◆ Retrospective data currently embargoed pending submission for publication



# Global Pivotal Trial in ICC

*A Randomized, Controlled Study to Compare the Efficacy, Safety and Pharmacokinetics of Melphalan/HDS Treatment Given Sequentially Following Cisplatin/Gemcitabine versus Cisplatin/Gemcitabine (Standard of Care) in Patients with Intrahepatic Cholangiocarcinoma*



- ◆ Leveraging existing network of leading cancer centers participating in Phase 3 OM Trial
- ◆ Sequential design requires minimal investment in 1H 2018

## Focused On Fastest Path To U.S. Market

EU & US Total Addressable Market			
Cancer Type	Annual Incidence <sup>1</sup>	Eligible PTS <sup>2</sup>	Annual Potential Market Opportunity (Millions) <sup>3,4</sup>
Ocular Melanoma	~4,700	~2,000	~\$80-\$200
Intrahepatic Cholangiocarcinoma (ICC)	~14,000	~9,300	~\$372-\$930
Colorectal (CRC)	411,000	40,000-55,000	~\$1,600-\$5,500
<b>Total EU &amp; U.S.</b>	<b>429,700</b>	<b>51,300-66,300</b>	<b>~\$2,052-\$6,630</b>

Orphan Indications

Notes:

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

## Recent Data Provides Confidence

*PD-L1 Expression In Tumor Metastasis Is Different Between Uveal Melanoma And Cutaneous Melanoma – A. Javed, D. Arguello, et al (Thomas Jefferson University, Caris Life Sciences) Immunotherapy, Nov 2017*

- ◆ PD-L1 expression on melanoma cells is significantly lower in metastatic uveal melanoma (MUM) as compared with metastatic cutaneous melanoma (MCM)
- ◆ Low PD-L1 expression in MUM likely explains its lack of response to treatment with PD-1 immune check-point inhibitors
- ◆ MUM also seems to demonstrate lesser PD-1 expressing tumor-infiltrating lymphocytes as compared with MCM
- ◆ Tumor cells in melanoma liver metastasis (both MUM and MCM) tend to demonstrate low PD-1 expression. This observation should be further explored in prospective studies investigating immune check-point inhibitor therapy to assess the utility of such treatments in the setting of liver metastases
- ◆ Studies of novel immunotherapeutic interventions in MUM should include a focus on developing modulators of the immune-suppressive environment of the liver

## Recent Data Provides Confidence

### *Percutaneous Hepatic Perfusion (PHP) for unresectable metastatic ocular melanoma to the liver: A Multi-institutional report of outcomes – Moffitt Cancer Center, University Hospital Southampton (Journal Surgical Oncology – Jan 2018)*

- ◆ 51 PTS treated between 2008 and 2016; (largest data set outside of a clinical trial)
- ◆ PTS received a total of 134 PHP TX (median TX = 2)
- ◆ Hepatic response to PHP was evaluable in 46 patients
  
- ◆ Results
  - ◆ 25 (49%) showed partial (N=22, 43.1%) or complete (N=3, 5.9%) hepatic response
  - ◆ 17 (33.0%) had stable disease  $\geq$  3 months
  - ◆ 82.4% hepatic disease control rate
  - ◆ Median follow up (367 days), PFS = 8.1 months, HPFS = 9.1 months; OS was 15.3 months
- ◆ Safety Analysis
  - ◆ 37.5% had Grade 3 or 4 non-hematologic toxicity
    - ◆ N=9 (17.6%) of PTS showed cardiovascular toxicity
  - ◆ 31.3% PTS showed Grade 3 or 4 neutropenia vs 85.7% in prior P3 trial
  - ◆ No TX related deaths
- ◆ Conclusion - results clearly demonstrate that PHP Therapy appears to be an effective means of obtaining rapid intrahepatic disease control, and is a sensible option in patients with predominant liver disease

### *Hepatic Progression-free and Overall Survival After Regional Therapy to the Liver for Metastatic Melanoma, Moffitt Cancer Center (AJCO)*

- ◆ Analysis of 3 non-randomized approaches for treatment of 30 patients with liver metastases primarily resulting from ocular melanoma and skin melanoma.
  - ◆ 10 PTS received PHP using melphalan
  - ◆ 12 PTS received chemoembolization (CE)
  - ◆ 6 PTS received radioembolization with yttrium-90 (Y90)
  - ◆ 2 PTS crossed over once their cancer progressed (1 from PHP to Y90; 1 from CE to PHP)
- ◆ Results:
  - ◆ PHP with Melphalan/HDS – Median OS 608 days, median HPFS 361 days, median PFS at 245 days
  - ◆ Y90 - Median OS 295 days, median HPFS 54 days, median PFS 54 days
  - ◆ CE – Median OS 265 days, median HPFS 80 days, median PFS 52 days
  - ◆ Side effects following all treatments were similar, with most complications recorded as anorexia, abdominal pain, fatigue and nausea. Laboratory irregularities, such as thrombocytopenia and abnormal liver function tests, were seen immediately after treatment in some patients, but returned to baseline within a few days



# CHEMOSAT<sup>®</sup>



- ◆ Presence established in several major markets (~22 cancer centers) ~500 commercial procedures performed
- ◆ German national reimbursement established after <3 years of commercial activity
- ◆ Added to Medical Oncology National Treatment Guidelines for Ocular Melanoma liver metastases in the Netherlands
- ◆ European centers producing data to support reimbursement applications in additional markets
- ◆ Commercial sales growing steadily; expanded reimbursement coverage in major EU countries required to expand commercial adoption



# European Commercialization

- ◆ ~ 500 commercial procedures performed
- ◆ EU physicians moving toward 2-3 initial TX as standard
- ◆ UK patient received record 8<sup>th</sup> TX in March 2017
- ◆ SPIRE Southampton (UK) and Hannover Medical School (Germany) have each performed >100 TX
- ◆ Established network of treating centers participating in pivotal trials
- ◆ Data from EU experience providing steady flow of supporting abstracts and publications

## Recent Financing and events

- ◆ \$5.0 million registered offering closed on Feb 9, 2018
  - ◆ 250.0 million units of one share of common stock (or pre-funded warrant) and one warrant to purchase two shares of common stock
  
- ◆ Filed a definitive proxy statement on Feb 26, 2018 seeking approval for:
  - ◆ increase in authorized shares of 500.0 million
  - ◆ reverse stock split of no at least 1:100 but no more than 1:500

## Cash & Capital Resources

Cash & Cash Equivalents	\$2.5 million at September 30, 2017
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Debt	None
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Shares Outstanding	435.0 million (480.0 million fully diluted <sup>1</sup> ) at Mar 1, 2018
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2016 Convertible Note	Extinguished December 2017
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1) Fully diluted includes approximately 38.0 million pre-funded warrants issued as part of our Feb 6, 2018 financing and 7.0 million warrants

## 2017 Highlights

- ◆ FY 2017 (9 mos) revenue increased ~53% to \$2.0 million over FY2016 total revenue
- ◆ National reimbursement coverage in Germany under ZE system
- ◆ Inclusion of CHEMOSAT in Medical Oncology National Treatment Guidelines for liver metastases in the Netherlands
- ◆ 2017 SPA agreement with FDA for pivotal trial of PHP with Melphalan/HDS in patients with ICC
- ◆ *Am. Journal of Clinical Oncology* publication of results from single-center retrospective review showed investigational PHP with Melphalan/HDS a doubling of OS and significantly longer PFS and HPFS compared with other targeted therapies
- ◆ Oral presentation of multi-center data at Regional Therapies meeting show strong tumor response, overall survival potential in PHP
- ◆ Two EU Hospitals each achieve 100<sup>th</sup> TX/8<sup>th</sup> patient TX milestones
- ◆ SPA Amendment approved expanding inclusion/exclusion criteria for extra hepatic metastases in the FOCUS trial
- ◆ Announced Exit from 2016 Convertible Note

## 2018 Milestones

- ◆ Dose first patient in Phase 3 ICC clinical trial
- ◆ Data publication from ICC retrospective analysis
- ◆ Data presentation from Phase 2 ICC Cohort
- ◆ Phase 3 OM Trial Update
- ◆ Presentations at major meetings (ECIO, SSO, CIRSE)

# Concentrating the Power of Chemotherapy™

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