
**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): February 11, 2019

DEL CATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-16133
(Commission
File Number)

06-1245881
(IRS Employer
Identification No.)

1633 Broadway, Suite 22C, New York, New York
(Address of principal executive offices)

10019
(Zip code)

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

None
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 8.01 Other Information.

On February 11, 2019, Delcath Systems, Inc. issued its most recent company presentation.

Item 9.01 Exhibit

Exhibit 99.1 [Company Presentation, dated February 11, 2019](#)

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: February 11, 2019

By: /s/ Jennifer Simpson

Name: Jennifer Simpson

Title: President and Chief Executive Officer



Delcath Investor Presentation

(OTCQB: DCTH)

February 2019

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: successful completion of the Company's Rights Offering and related transactions and the amount of gross proceeds, if any; the timing and results of future clinical trials including without limitation the OM and ICC 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, inclusion in the German and Dutch national treatment guidelines, 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, 2017, and our Reports on Form 10-Q for the first three quarters and all Form 8-K filings made in 2018.

Management Team

◆ Jennifer Simpson, PhD., M.S.N., C.R.N.P. - President & Chief Executive Officer

Named President and CEO of Delcath in May of 2015. Dr. Simpson previously served as Interim President and Chief Executive Officer of Delcath and as Interim Co-President and Co-Chief Executive Officer. She joined Delcath in 2012 as Executive Vice President, Global Marketing.

Prior to joining Delcath Dr. Simpson served as the Vice President, Global Marketing, Oncology Brand Lead at ImClone Systems, Inc., where she was responsible for all product commercialization activities and launch preparation for one of the late stage assets. From 2009 to 2011, Dr. Simpson served as the Vice President, Product Champion and from 2008 to 2009 as the Associate Vice President, Product Champion for a late stage asset at ImClone. From 2006 to 2008 Dr. Simpson served as Product Director, Oncology Therapeutics Marketing at Ortho Biotech. Earlier in her career Dr. Simpson spent over a decade as a hematology/oncology-nurse practitioner and educator. Dr. Simpson earned a Ph.D. in Epidemiology from the University of Pittsburgh, an M.S. in Nursing from the University of Rochester, and a B.S. in Nursing from the State University of New York at Buffalo.

◆ John Purpura, Executive Vice President - Global Head of Operations

Joined Delcath as Executive Vice President for Regulatory Affairs and Quality Assurance in November 2009, and was promoted to Executive Vice President - Global Head of Operations in July 2016.

Previously Mr. Purpura was with Bracco/E-Z-EM as Vice President and then Executive Director of International Regulatory Affairs from 2007 to 2008, and Head of Regulatory Affairs for North America and Latin America from 2008 to October 2009. Prior to E-Z-EM, Mr. Purpura had an 11-year career with Sanofi-Aventis with progressively more senior Regulatory and CMC responsibilities, ultimately serving as Associate Vice President for Regulatory and CMC from 2005 to 2007. Prior to Sanofi, Mr. Purpura held various quality and regulatory management roles with Pharma companies from 1985 to 1995. He earned a MS in Management & Policy and BS degrees in Chemistry and Biology at the State University of New York at Stony Brook.

◆ Barbra C. Keck, Chief Financial Officer

Joined Delcath as Controller in January 2009, was promoted to Vice President in October 2009, to Senior Vice President in March 2015, and the Chief Financial Officer in February 2017.

Prior to joining Delcath, she worked with Deloitte & Touche, LLP. Earlier in her career, Ms. Keck spent several years in the non-profit sector, including Young Audiences New York and the Muse Machine. She earned her M.B.A. in Accountancy from Baruch College and Bachelor of Music in Music Education from the University of Dayton.

Delcath Systems

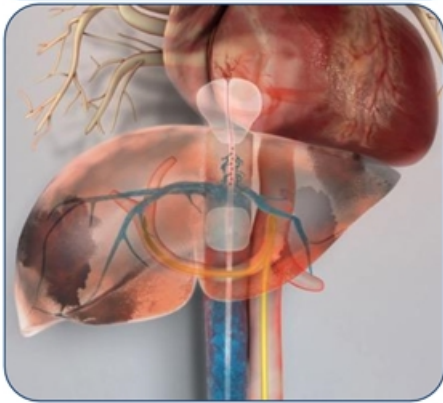
- ◆ Interventional oncology company focused on treatment of primary/metastatic liver cancers
- ◆ Proprietary percutaneous hepatic perfusion (PHP) system delivers high-dose chemotherapy (melphalan) directly to the liver with extra-corporeal filtration to minimize systemic toxicity
- ◆ Commercial stage in the EU under the CHEMOSAT® brand
- ◆ Late-stage (Phase 3) clinical development in the US (Melphalan/HDS)
- ◆ Pursuit of orphan indications in metastatic ocular melanoma (mOM) and intrahepatic cholangiocarcinoma (ICC)

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

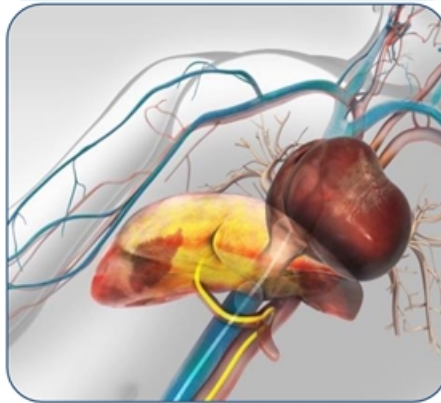
Our Solution – Liver Focused Disease Control

- ◆ 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

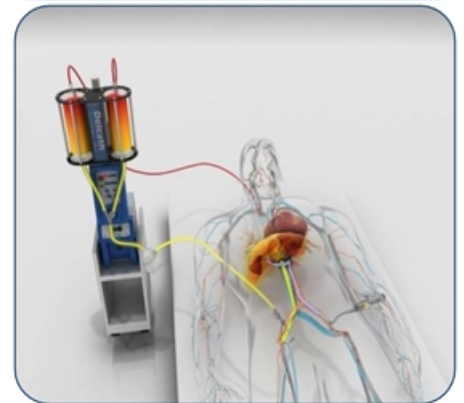
Liver Isolated Via Double Balloon Catheter In IVC



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 are limited

* SOURCE – 2008 GLOBOCAN

Limitations of Current Liver Cancer Treatments

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

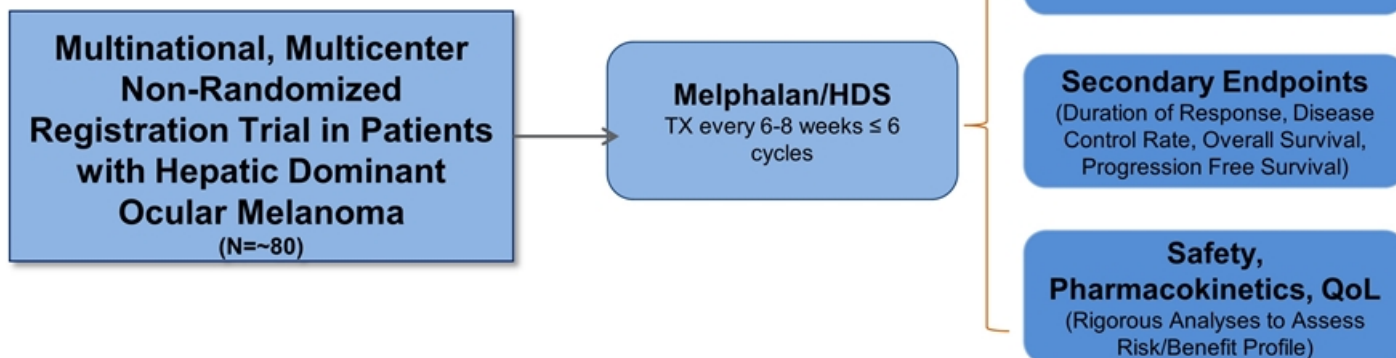
Building Shareholder Value Through Clinical Development

Tumor Type	Program	Notes	Milestones
Ocular Melanoma (OM)	FOCUS Trial P3 Pivotal Study in Hepatic Dominant OM	<ul style="list-style-type: none"> Fastest Path to U.S. Market Approval Amended Protocol July 2018 	<ul style="list-style-type: none"> ✓ FPI Amended Trial ✓ Interim Safety Analysis Aug 2018 • Rollout of amended protocol
Intrahepatic Cholangiocarcinoma (ICC)	ALIGN Trial P3 Pivotal Trial in ICC	<ul style="list-style-type: none"> FDA SPA 2017 Strong Signal in Commercial Setting Value Driver 	<ul style="list-style-type: none"> ✓ Enrollment open ✓ First PTS TX
Hepatocellular Carcinoma (HCC)	201 HCC Trial (US Only)	ICC Cohort Fully Enrolled	<ul style="list-style-type: none"> ✓ ICC Data Published in European Journal of Radiology
	202 HCC/ICC Trial (EU Only)	HCC Remains Closed to Enrollment	

Amended Global Phase III Clinical Trial



Clinical Trial For Patients with
Hepatic-Dominant Ocular Melanoma



Summary of Changes

- ◆ Non-randomized, single-arm trial
- ◆ PTS treated in prior randomized protocol continue to be treated/evaluated
- ◆ Prior enrollment counted to amended enrollment target
- ◆ Anticipate completing enrollment by end June 2019

Recent Data Provides Confidence: Overall Survival Signal

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

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-L1 immune check-point inhibitors
- ◆ MUM also seems to demonstrate lesser PD-L1 expressing tumor-infiltrating lymphocytes as compared with MCM
- ◆ Tumor cells in melanoma liver metastasis (both MUM and MCM) tend to demonstrate low PD-L1 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

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
- ◆ 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 ≥ 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

Percutaneous Hepatic Perfusion in Patients with Unresectable Liver Metastases from Ocular Melanoma using Delcath Systems' Second Generation (GEN 2) Hemofiltration System: A Prospective Phase 2 Study - Leiden University Medical Center (LUMC), The Netherlands (2018 CIRSE Annual Conference-Poster Presentation)

- ◆ 35 PTS treated at LUMC (2/2014 – 6/2017)
- ◆ study prospectively evaluated tumor response rate, safety, OS, PFS, hPFS
- ◆ PTS received max 2 PHP TX per protocol; 67 PHP TX were administered to the 35 PTS in the study
- ◆ Post-TX assessments possible in 32 PTS
- ◆ Results according to RECIST 1.1
 - ◆ CR observed in one patient (3.1%)
 - ◆ PR observed in 21 PTS (65.6%)
 - ◆ ORR 68.7%
 - ◆ SD observed in four PTS (12.5%),
 - ◆ DCR was 81.2%
 - ◆ Median OS was 15.6 months, median PFS was 8.6 months, and median hPFS was 10.8 months
- ◆ Safety analysis showed 14 serious AEs, no deaths, no severe bleeding complications, myocardial or cerebral infarctions observed
- ◆ Hematologic toxicities of Grade 3/4 were observed in most patients, with 18 (54.5%) PTS experiencing thrombocytopenia and 22 PTS (66.7%) experiencing neutropenia.
- ◆ Hematologic events were manageable or self-limiting; no grade 3/4 hepatic serious AEs were observed
- ◆ investigators concluded PHP Therapy was shown to have a manageable adverse event profile and to be a potentially valuable treatment for certain PTS with OM liver metastases

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 published in European Journal of Radiology
- ◆ KOL agreement that ***“CHEMOSAT treatment does, indeed, demonstrate an efficacy signal in ICC and is worthy of full clinical investigation”***

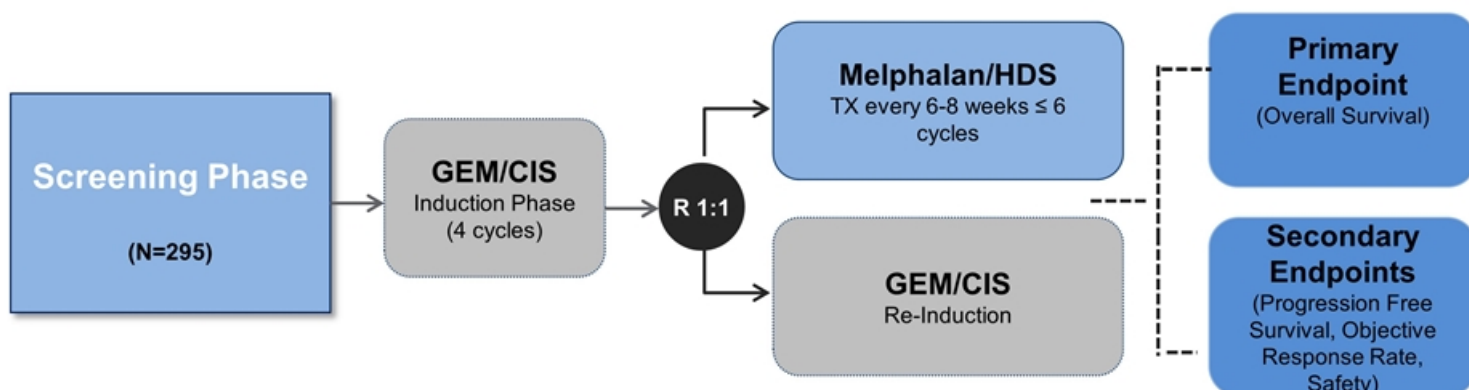
Percutaneous Hepatic Perfusion (Chemosaturation) with Melphalan in Patients with Intrahepatic Cholangiocarcinoma: European Multicentre Study on Safety, Short Term Effects and Survival, European Radiology 2018, Marquardt, et al

- ◆ Study evaluated 15 PTS with ICC selected for PHP TX after failing prior therapies; PTS TX at nine hospitals in Europe between 2012 and 2016
- ◆ TX outcomes assessed by imaging every three mos following PHP TX
- ◆ Results after the first PHP TX:
 - ◆ one patient (7%) CR, two PTS (13%) had PR, and SD observed in eight PTS (53%); CR patient not retreated and is still alive
 - ◆ Control rate (CR+PR+SD) was 73%
 - ◆ Three PTS (20%) progressed after the first TX; and one patient died prior to post-procedure imaging
 - ◆ Five PTS with SD received a second PHP TX, resulting in one PR (20%), three SD (60%), and one PD (20%); During the follow-up phase two of the SD PTS received additional PHP treatments
 - ◆ Median OS was 26.9 months from initial diagnosis and 7.6 months from first PHP TX
 - ◆ One-year OS from first PHP TX was 40%, Median PFS was 122 days, and median hepatic hPFS was 131 days
- ◆ Side-effects were potentially under-reported but were considered by the investigators to be tolerable and comparable to other systemic and local therapies
- ◆ Practitioners observed no Grade 3/4 AEs during the PHP procedure; significant hematological toxicity was observed post-procedure in the form of anemia and thrombocytopenia 5-7 days after the PHP TX
- ◆ Investigators concluded that PHP Therapy provides “promising response rates in patients with ICC,” and that side-effects were tolerable and comparable to other treatment strategies

The ALIGN Trial - 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
- ◆ Continue to open centers utilizing efficient allocation of resources

Focused On Fastest Path To U.S. Market

EU & US Total Addressable Market			
Cancer Type	Annual Incidence ¹	Eligible PTS ²	Annual Potential Market Opportunity (Millions) ^{3,4}
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
Total EU & U.S.	429,700	51,300-66,300	~\$2,052-\$6,630

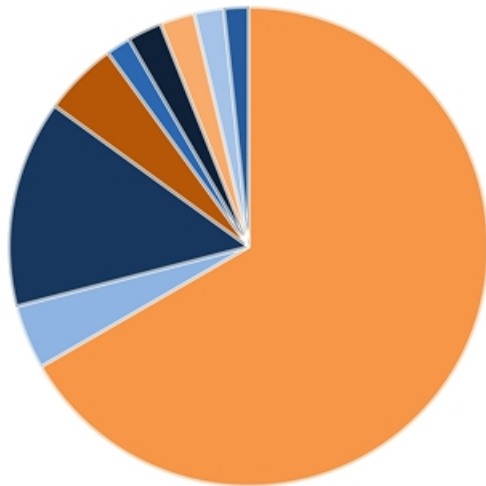
Orphan Indications

Notes:

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

CHEMOSAT®

Tumor Types Treated



■ OM Mets
 ■ HCC
 ■ ICC
 ■ CRC
 ■ Breast
■ Pancreatic
 ■ mNET
 ■ Cutaneous
 ■ Other

- ◆ Device label permits use in broad range of primary & metastatic liver cancers
- ◆ 13 tumor types treated since CHEMOSAT launch
- ◆ Presence established in several major markets (~22 cancer centers)
- ◆ ~600 commercial procedures performed
- ◆ German Guidelines Program in Oncology added CHEMOSAT to national treatment guidelines for metastatic melanoma
- ◆ 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
- ◆ Data from EU experience providing steady flow of supporting abstracts and publications



medac

medac. Working together
for sharper focus on patients.

- ◆ Licensing agreement announced December 2018
- ◆ €6 million in upfront and milestone payments
- ◆ Fixed transfer price and royalty payments
- ◆ Agreement includes EU member states plus United Kingdom, Norway, Switzerland, Liechtenstein
- ◆ Extensive network throughout Europe
- ◆ Allows Delcath to focus on Clinical Development Program

Recent Financing Activity

- ◆ Sold \$5.0 million of common stock and warrants in Feb 2018 for net proceeds of approx. \$4.6 million
- ◆ Issued \$9.4 million in convertible notes and warrants between June – September 2018 for net cash proceeds of approx. \$6.3 million
- ◆ \$50.0 million rights offering & backstop commitment announced in July 2018
 - ◆ Offered up to 28.6 million shares of common stock at subscription price of \$1.75/share
 - ◆ Rights offering closed in September with gross proceeds of \$8.2 million
 - ◆ Backstop commitment terminated on January 18, 2019
- ◆ Issued Series D Preferred Stock for gross proceeds of \$1.2 million
 - ◆ Converts to common stock at \$0.61/share
- ◆ \$100.0 million Form S-3 effective in December 2018

Cash & Capital Resources

Cash	\$8.9 million at September 30, 2018
Shares Outstanding	11.2 million (76.0 million fully diluted ¹) at January 18, 2019
Debt	\$4.5 million at November 30, 2018

1) Fully diluted includes approximately 64.8 million warrants

2018 Milestones

- ◆ medac Licensing Agreement
- ◆ Dose first patient in Phase 3 ICC clinical trial
- ◆ Data publication from ICC retrospective analysis
- ◆ Phase 3 OM Trial Amendment
- ◆ Presentations at major meetings (ECIO, SSO, CIRSE)

Summary

- ◆ Late-stage clinical development with OM registration trial expected to complete accrual in June 2019
- ◆ Focused on cancers of the liver with high unmet medical need & no established SOC
- ◆ Commercial experience from Europe & recent clinical data provide confidence in clinical development path
- ◆ Pursuing indications representing ~\$1 billion opportunity in the U.S. & Europe

Concentrating the Power of Chemotherapy™

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