



## Delcath Reports 2014 Third Quarter Results

November 5, 2014

- Conference Call and Webcast Today at 4:30 p.m. ET -

NEW YORK, Nov. 5, 2014 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH) today reported financial results for the fiscal third quarter ended September 30, 2014. Developments for the quarter and recent weeks subsequent to quarter end are as follows:

### Summary of Clinical Development Program, Recent Highlights, and Anticipated Milestones

#### *Global Phase 2 Hepatocellular Carcinoma (HCC) Trial*

- Commencement of Phase 2 HCC trial in Europe and the United States
- Johannes Wolfgang Goethe University Hospital (Frankfurt) & Moffitt Cancer Center (Tampa, FL) open for enrollment
- Preparing to expand Phase 2 trial to include intrahepatic cholangiocarcinoma (ICC) cohort in European trial
- Interim data readout on first 11 HCC patients expected end of Q2 2015

#### *Global Phase 3 Clinical Trial Ocular Melanoma (OM) Liver Metastases*

- Planning to initiate Global Phase 3 clinical trial in ocular melanoma (OM) liver metastases
- Preparing to submit meeting request to FDA by end of year; expect meeting in Q1 2015
- Expect trial to commence in mid-2015

#### *Other Data Collection & Highlights*

- Investigator Initiated Trials (IITs)
  - University of Leiden colorectal cancer metastatic to the liver (mCRC); six patients of approximately 30 enrolled and treated
  - Johannes Wolfgang Goethe (JWG); HCC trial open for enrollment
- European Prospective Patient Registry; enrollment to commence by year end
- Presentation of positive CHEMOSAT/Melphalan/HDS data at European Society of Surgical Oncology (ESSO) Congress

"In recent weeks, we've taken significant steps to enhance our clinical development program," said Dr. Jennifer Simpson, interim CEO and President of Delcath Systems. "Our Global Phase 2 HCC clinical trial is now open for enrollment in both Europe and the United States. We are also preparing to expand the program to include a cohort of patients with ICC in the European trial. Additionally, we have initiated planning for a Global Phase 3 trial in OM liver metastases with a view to beginning the trial in mid-2015. We believe this clinical trial could represent the fastest potential route to NDA approval in the United States. Together with the investigator initiated trials we are currently supporting and the prospective European patient registry we expect to activate soon, these trials form a robust clinical development strategy designed to generate data in multiple tumor types."

"Commercially, steady progress continues to be made with the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT) in Europe," Dr. Simpson continued. "Through the end of October, 62 CHEMOSAT treatments have been performed in 2014, double the amount performed over the same period in 2013. Interest in CHEMOSAT for the treatment of cancers in the liver continues to grow, as is reflected in the inclusion of three positive abstracts on the therapy in the scientific program of the recent ESSO Congress."

### Financial Results

For the third quarter ended September 30, 2014, Delcath generated total product revenue of \$217,000 compared to \$72,000 in the year-ago third quarter. Operating expenses decreased by approximately 24% to \$5.2 million from \$6.8 million for the same period in 2013. The decrease is primarily due to a significant reduction in research and development expenses related to the phasing out of the Company's medical science liaison program and the Company's successful efforts to increase organizational efficiencies. Operating loss was \$5.1 million during the third quarter, as compared with an operating loss of \$6.7 million in the same period of the prior year.

For the nine months ended September 30, 2014, total product revenue was \$778,000 compared with \$152,000 in the year-ago same period. Operating expenses decreased by approximately 40% to \$16.6 million from \$27.6 million for the first nine months of 2013. The decrease is related to costs incurred for the Company's NDA submission to the FDA in 2013, the phasing out of the Company's medical science liaison program and the Company's successful efforts to increase organizational efficiencies. The operating loss for the first nine months of 2014 was \$16.0 million as compared with \$27.5 million for the first nine months of 2013.

Cash and cash equivalents as of September 30, 2014 were \$23.3 million. During the first nine months, net cash used in operating activities was \$12.4 million, a 57% reduction compared to \$28.9 million in the comparable period in 2013. The decrease in cash utilization was in part due to a reduction in NDA submission-related costs, and improved organizational and operational efficiencies.

### Conference Call and Webcast

The Company will host a conference call today, November 5, 2014 at 4:30 p.m. ET to discuss its financial results for the third quarter ended September

30, 2014, and provide an update on recent corporate progress.

The dial-in numbers for the conference call are 877-474-9503 (U.S. participants) and 857-244-7556 (international participants); both numbers require passcode: 93311476. To access the live webcast, go to the Events & Presentations page on the Investor Relations section of the Company's website at <http://www.delcath.com/investors/events/>.

During the call management will offer remarks on the Company's third quarter financial results and recent corporate developments as well as answer questions received via email from participants. Questions may be sent to [mpolyviou@evcgroup.com](mailto:mpolyviou@evcgroup.com) between 4:05 to 4:30pm today, Wednesday, November 5th. There can be no assurance that all questions will be selected to be presented on the conference call.

A taped replay of the call will be available beginning approximately two hours after the call's conclusion and will be available for seven days. Dial-in numbers for the replay are 888-286-8010 and 617-801-6888 for U.S. and International callers, respectively. The replay passcode for both U.S. and International callers is 38471263. An archived webcast will also be available at <http://www.delcath.com/investors/events/>.

#### About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary product-Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS)-is designed to administer high dose chemotherapy to the liver, while controlling the systemic exposure to those agents. The Company's principal focus is on the treatment of primary and metastatic liver cancers. In the United States, the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). The Melphalan/HDS system has not been approved for sale in the United States. In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe. The Company has commenced a global phase 2 clinical trial in Europe to investigate Melphalan/HDS system for primary liver cancer and is initiating plans to evaluate intrahepatic cholangiocarcinoma.

*Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the timing and results of the Company's clinical trials including without limitation the HCC, ICC, and OM clinical trial programs, timely enrollment and treatment of patients in the Global Phase 2 HCC and ICC clinical trial, FDA approval of the Global Phase 3 OM clinical trial protocol, IRB or ethics committee clearance of the Phase 2 HCC/ICC and/or Phase 3 OM protocols from participating sites and the timing of site activation and subject enrollment in each trial, the impact of the presentations at ESSO and future clinical results consistent with the data presented, approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure, the impact, if any, of Value 4 status on potential CHEMOSAT product use and sales in Germany, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK, the Company's ability to successfully commercialize the Melphalan HDS/ CHEMOSAT system and the potential of the Melphalan HDS/CHEMOSAT system as a treatment for patients with primary and metastatic disease in the liver, our ability to obtain reimbursement for the CHEMOSAT system in various markets, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter and provide the same in a timely manner, approval of the current or future Melphalan HDS/CHEMOSAT system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, the Company's 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, our ability to maintain NASDAQ listing, and uncertainties regarding the Company's ability to obtain financial and other resources for any research, development, clinical trials and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.*

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**Delcath Systems, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**for the three and nine months ended September 30, 2014 and 2013**  
**(Unaudited)**  
(in thousands, except share and per share data)

	Three months ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Product revenue	\$ 217	\$ 72	\$ 778	\$ 152
Other revenues	-	-	-	300
Total revenue	217	72	778	452
Cost of goods sold	(50)	(23)	(209)	(386)
Gross profit	167	49	569	66
Selling, general and administrative <sup>1</sup>	4,538	4,573	12,956	16,919
Research and development <sup>1</sup>	683	2,178	3,632	10,639
Total operating expenses	5,221	6,751	16,588	27,558

Loss from operations	(5,054)	(6,702)	(16,019)	(27,492)
Change in fair value of warrant liability, net	519	(497)	1,612	2,345
Interest income	2	2	4	18
Other expense and interest expense	(25)	(9)	(33)	(404)
Net loss	\$ <u>(4,558)</u>	\$ <u>(7,206)</u>	\$ <u>(14,436)</u>	\$ <u>(25,533)</u>
Loss Per Common Share				
Basic and diluted loss per common share*	\$ <u>(0.48)</u>	\$ <u>(1.15)</u>	\$ <u>(1.54)</u>	\$ <u>(4.35)</u>
Weighted Average Common Shares				
Basic and diluted weighted average common shares outstanding*	<u>9,447,887</u>	<u>6,254,312</u>	<u>9,391,793</u>	<u>5,875,490</u>
Other Comprehensive Income (Loss)				
Foreign currency translation adjustments	\$ <u>(6)</u>	\$ <u>15</u>	\$ <u>(27)</u>	\$ <u>384</u>
Comprehensive loss	\$ <u>(4,564)</u>	\$ <u>(7,191)</u>	\$ <u>(14,463)</u>	\$ <u>(25,149)</u>

Note 1:

Operating expenses include non-cash stock-based compensation as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Selling, general and administrative	\$ 72	\$ (159)	\$ 313	\$ 370
Research and development	28	(67)	104	216
Total stock-based compensation expense	\$ <u>100</u>	\$ <u>(226)</u>	\$ <u>417</u>	\$ <u>586</u>

\* Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.

**DELCATH SYSTEMS, INC.**  
**Condensed Consolidated Balance Sheets**  
**as of September 30, 2014 and December 31, 2013**  
**(Unaudited)**  
(in thousands, except share data)

	September 30, 2014	December 31, 2013
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 23,323	\$ 31,249
Accounts receivables, net	157	349
Inventories, net	518	719
Prepaid expenses and other current assets	752	1,711
Total current assets	<u>24,750</u>	<u>34,028</u>
Property, plant and equipment, net	2,118	3,069
Total assets	<u>\$ 26,868</u>	<u>\$ 37,097</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 114	\$ 582
Accrued expenses	4,426	3,740
Warrant Liability	555	2,310
Total current liabilities	<u>5,095</u>	<u>6,632</u>
Other non-current liabilities	1,088	366
Total liabilities	<u>6,183</u>	<u>6,998</u>
Commitments and contingencies	—	—
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	—	—

Common stock, \$.01 par value; 170,000,000 shares authorized; 9,515,175 and 8,394,397 shares issued and 9,448,903 and 8,392,641 shares outstanding at September 30, 2014 and December 31, 2013, respectively \*

Additional paid-in capital

95 84

264,140 259,102

Accumulated deficit

(243,568) (229,132)

Treasury stock, at cost; 1,757 shares at September 30, 2014 and December 31, 2013, respectively

(51) (51)

Accumulated other comprehensive income

69 96

Total stockholders' equity

20,685 30,099

Total liabilities and stockholders' equity

\$ 26,868 \$ 37,097

\* Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.

SOURCE Delcath Systems, Inc.