Delcath Reports 2015 First Quarter Financial Results

May 6, 2015

Record quarterly product revenue indicates progress in Europe with adoption of Company's chemosaturation therapy to treat liver cancers

NEW YORK, May 6, 2015 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on oncology with an emphasis on the treatment of primary and metastatic liver cancers, announces financial results for the three months ended March 31, 2015.

Highlights of the first quarter and recent weeks include:

- Achieved quarterly product revenue of $0.44 million, an increase of more than 43% compared with the first quarter of 2014;
- Activated a prospective patient registry in Europe to collect uniform essential patient safety, efficacy and Quality of Life (QoL) information from commercial cases;
- Received approval to expand the global Phase 2 hepatocellular carcinoma (HCC) program to include patients with intrahepatic cholangiocarcinoma (ICC) in Europe;
- Expanded the global Phase 2 program for the treatment of patients with unresectable HCC or primary liver cancer with the addition of Montefiore Medical Center in the Bronx, New York;
- Reported the submission of the manuscript of its Phase 3 clinical trial data with Melphalan/HDS for publication in a leading peer-reviewed medical journal;
- Affirmed Value 4 coverage status for the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT) by the German federal reimbursement agency for 2015; and
- Raised gross proceeds of $2.8 million through a public offering of common stock and warrants.

"2015 is off to a strong start with important advances in commercial and clinical programs, and the recent reduction in operating expenses," said Jennifer Simpson, Ph.D., MSN, CRNP, Interim President and Chief Executive Officer of Delcath. "This record quarterly product revenue highlights the growing interest in CHEMOSAT in Europe and continued market adoption. The initiation of our European patient registry will allow us to benefit from the ongoing commercial utilization of CHEMOSAT by providing important outcomes data that should be instrumental in furthering both reimbursement and market adoption.

"We are particularly pleased with the significant progress we've made with our clinical development program. We expanded our global Phase 2 HCC clinical program to include an ICC cohort and we also added Montefiore Medical Center, a nationally recognized Center of Excellence for cancer care and clinical research. We believe the consolidated safety data from the HCC and ICC cohorts will offer valuable information for us to provide to the FDA.

"We remain on track to initiate a global pivotal Phase 3 overall survival clinical trial in ocular melanoma (OM) that has metastasized to the liver by the end of 2015. Statistically significant hepatic progression-free survival data in OM metastases achieved in our previous Phase 3 clinical trial, combined with positive patient outcomes and improved safety profile demonstrated in more than 100 patients treated in commercial settings in Europe and our U.S. Expanded Access Program, give us confidence this Phase 3 program offers the fastest path to potential approval of Melphalan/HDS in the U.S.

"We expect to achieve a number of important milestones throughout the balance of 2015 that should advance the Company's mission to bring our CHEMOSAT/Melphalan/HDS therapy to benefit patients with cancers of the liver worldwide," concluded Dr. Simpson.

First Quarter Financial Results

Total revenue for the first quarter of 2015 of $0.4 million increased 43% from $0.3 million for the first quarter of 2014. Selling, general and administrative expenses during the first quarter of 2015 were $3.0 million compared with $3.8 million in the year-ago period. During the first quarter of 2015, the Company recorded workforce restructuring charges of $0.4 million. Excluding those

charges, selling, general and administrative expenses were $2.6 million for the first quarter of 2015, compared with $3.8 million for the first quarter of 2014, a decrease of $1.2 million.

Total operating expenses for the first quarter of 2015 decreased by 25% to $4.0 million from $5.3 million for the same period in 2014. This decrease reflects a reduction in severance and compensation-related expenses following significant workforce restructurings throughout 2014 and into 2015.

The Company recorded a net loss for the first quarter of 2015, of $3.5 million, a decrease of $1.8 million, or 34%, compared with a net loss of $5.3 million for the same period in 2014. This decrease is primarily due to a $1.2 million reduction in operating expenses, a $0.1 million improvement in gross profit and a $0.4 million favorable change in the fair value of the warrant liability, a non-cash item.

Balance Sheet Highlights

Cash and cash equivalents as of March 31, 2015 were $18.5 million, compared with $20.5 million as of December 31, 2014. During the first quarter of 2015, net cash used in operating activities was $4.4 million.

On February 11, 2015 Delcath raised gross proceeds of $2.8 million in a public offering of common stock and warrants.

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with a principal focus on the treatment of primary and metastatic liver cancers. Our proprietary 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 systemic exposure. In April 2012 we obtained authorization to affix a CE Mark to our second-generation system, which is currently marketed in Europe as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In the U.S. Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the U.S. Food and Drug Administration (FDA). Melphalan/HDS has not been approved for sale in the U.S. We have commenced a global Phase 2 clinical trial in Europe and the U.S. to investigate Melphalan/HDS for the treatment of primary liver cancer (hepatocellular carcinoma or HCC), and have expanded the study to include a cohort of patients with intrahepatic cholangiocarcinoma (ICC). We are also advancing plans to conduct a global Phase 3 trial in ocular melanoma that has metastasized to the liver.

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 and European Health Authority 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, acceptance of the Phase 3 manuscript at a leading peer reviewed medical journal and the impact of publication to support the Company's business, 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 U.S. 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 Balance Sheets
(in thousands, except share data)

	March 31, 2015	December 31, 2014
	(Unaudited)	
Assets:		
Current assets		
Cash and cash equivalents	$ 18,462	$ 20,469
Accounts receivables, net	312	174
Inventories	274	349
Prepaid expenses and other current assets	982	974
Total current assets	20,030	21,966
Property, plant and equipment, net	1,620	1,798
Total assets	$ 21,650	$ 23,764
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$ 268	$ 748
Accrued expenses	3,135	3,603
Warrant liability	836	225
Total current liabilities	4,239	4,576
Other non-current liabilities	987	1,043
Total liabilities	5,226	5,619
Commitments and Contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	--	--
Common stock, $.01 par value; 170,000,000 shares authorized; 12,200,397 and 9,740,397 shares issued and 12,169,706 and 9,708,841 shares outstanding at March 31, 2015 and December 31, 2014, respectively	122	97
Additional paid-in capital	266,349	264,592
Accumulated deficit	(250,002)	(246,513)
Treasury stock, at cost; 1,757 shares at March 31, 2015 and December 31, 2014, respectively	(51)	(51)
Accumulated other comprehensive income	6	20
Total stockholders' equity	16,424	18,145
Total liabilities and stockholders' equity	$ 21,650	$ 23,764

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three months ended March 31, 2015	2014
Revenue	$ 444	$ 310
Cost of goods sold	133	93
Gross profit	311	217
Operating expenses:		
Selling, general and administrative	3,040	3,819
Research and development	979	1,457
Total operating expenses	4,019	5,276
Operating loss	(3,708)	(5,059)
Change in fair value of the warrant liability, net	209	(205)
Interest income	2	1
Other income (expense) and interest income (expense)	9	(15)
Net loss	$ (3,488)	$ (5,278)
Other comprehensive income (loss):		

Foreign currency translation adjustments	$ (14)	$ (2)
Comprehensive loss	$ (3,502)	$ (5,280)
Common share data:		
Basic and diluted loss per share	$ (0.32)	$ (0.57)
Weighted average number of basic and diluted common shares outstanding	10,857,142	9,300,078

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