Delcath Reports 2014 Fourth Quarter And Full Year Financial Results

March 10, 2015

NEW YORK, March 10, 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 and 12 months ended December 31, 2014.

Highlights of 2014 and recent weeks include:

- Opened for enrollment a global Phase 2 clinical trial program for Melphalan/HDS for first-line treatment of patients with unresectable hepatocellular carcinoma (HCC) or primary liver cancer at leading cancer centers in Europe and at the Moffitt Cancer Center, the first U.S. clinical site;
- Achieved product revenue of $1.1 million in 2014, an increase of more than 100% compared with product revenue of $490,000 in 2013;
- Submission of the manuscript of its Phase 3 clinical trial data with the Delcath Hepatic Delivery System (Melphalan/HDS) for publication in a peer-reviewed medical journal;
- Selection of a poster highlighting Melphalan/HDS for treatment of melanoma liver metastases for presentation at the 2015 Society of Surgical Oncology Annual Meeting;
- Presentation of data highlighting positive clinical experiences with Melphalan/HDS from three leading cancer hospitals at the 2014 European Society of Surgical Oncology (ESSO) congress;
- Affirmed Value 4 coverage status for the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT) by the German federal reimbursement agency for 2015;
- Raised gross proceeds of $2.8 million through a public offering of common stock and warrants;
- Reorganized and strengthened its Board of Directors by appointing Dr. Roger G. Stoll as Executive Chairman and adding three new Directors: Dr. Dennis H. Langer, William D. Rueckert and Dr. Marco Taglietti.

"Throughout 2014, we continued to make progress across all areas important to our strategic plan including clinical, commercial, and corporate initiatives," said Jennifer Simpson, Ph.D., MSN, CRNP, Interim President and Chief Executive Officer of Delcath.

"We are pleased with the continued sales growth of CHEMOSAT in Europe. During the year, 79 treatments were performed compared with 40 in 2013, underscoring growing interest and adoption in our key European markets. Submission of our Phase 3 data for publication in a peer-reviewed journal is another key milestone for Delcath. If published, this article will be a significant tool in support of our efforts to obtain reimbursement in a number of European countries. Together with inclusion of our results in important medical and scientific programs, such as the 2014 ESSO Congress and the upcoming 2015 SSO Congress, we believe publication of our data will continue to increase awareness of the value of this therapy.

"Our global Phase 2 HCC clinical trial program is now open for enrollment with the initial patients being treated in Europe. We look forward to adding additional European and domestic sites to this study and are preparing to expand the program to include a cohort of patients with intrahepatic cholangiocarcinoma (ICC) in the European segment of this trial.

"We are advancing plans to initiate a pivotal Phase 3 clinical trial in ocular melanoma (OM) that is metastatic to the liver with overall survival as the primary endpoint. Based on the strength of the hepatic progression free survival efficacy data in OM metastases obtained in our previous Phase 3 clinical trial, and the reports of an improved safety profile from more than 100 patients treated in commercial settings in Europe, we believe this Phase 3 program offers the fastest path to potential approval of Melphalan/HDS in the U.S.," concluded Dr. Simpson.

Fourth Quarter Financial Results

Total revenue in the fourth quarter of 2014 of $0.3 million was comparable to total revenue of $0.3 million in the fourth quarter of 2013. Selling, general and administrative expenses decreased to $2.8 million in the fourth quarter of 2014 from $3.7 million in the fourth quarter of 2013. Research and development expenses in the fourth quarter of 2014 decreased to $0.7 million from $2.0 million in the same period a year ago.

Total operating expenses for the fourth quarter of 2014 decreased by approximately 40% to $3.5 million from $5.8 million for the same period in 2013. The decrease reflects a reduction in severance and compensation related expenses following the company's significant work force restructurings throughout 2013 and 2014.

For the fourth quarter of 2014, the Company recorded a net loss of $2.9 million or $0.31 per share, a decrease of approximately 40%, compared with a net loss of $4.8 million or $0.63 per share.

2014 Financial Results

Total revenue in 2014 was $1.1 million compared with $0.8 million in 2013, of which $0.3 million related to the recognition of previously deferred revenue.

Selling, general and administrative expenses decreased to $15.8 million in 2014 from $20.7 million in 2013. The decrease reflects a reduction in severance and compensation-related expenses following the Company's workforce restructurings throughout 2013, partially offset by the recognition

in 2014 of $1.3 million in expenses related to vacating the Company's previous corporate office space.

Research and development expenses decreased to $4.3 million in 2014 from $12.7 million in 2013, primarily due to a significant reduction in regulatory and clinical expenses related to the Company's New Drug Application (NDA) submission to the FDA, as well as a reduction in severance and compensation- related expenses following significant workforce restructurings throughout 2013.

Operating expenses decreased by approximately 40% to $20.1 million in 2014 from $33.3 million in 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 in 2014 was $19.3 million, compared with $33.0 million in 2013.

Delcath recorded a net loss in 2014 of $17.4 million or $1.84 per share, a decrease of $12.9 million, or 43%, compared with a net loss in 2013 of $30.3 million or $4.81 per share. The narrowing of the net loss is primarily due to a $13.3 million decrease in operating expenses in 2014.

Balance Sheet Highlights

Cash and cash equivalents as of December 31, 2014 were $20.5 million, compared with $31.2 million as of December 31, 2013. During 2014, net cash used in operating activities was $15.6 million, a 54% reduction compared with $34.1 million used in 2013. The decrease in cash utilization was due in part to a reduction in NDA submission-related costs, and improved organizational and operational efficiencies.

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

Conference Call

Delcath management intends to host periodic "Business and Clinical Update" conference calls in the future, which will allow management to time such updates to meaningful corporate and clinical developments.

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 we are planning to evaluate patients with intrahepatic cholangiocarcinoma (ICC) in a Phase 2 clinical study. 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, the impact of the presentations at ESSO and SSO 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 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.

Contact Information:
Anne Marie Fields
LHA
212-838-3777
afields@lhai.com

-Tables to Follow-

Delcath Systems, Inc.
Consolidated Statements of Operations and Comprehensive Loss
for the three and twelve months ended December 31, 2014 and 2013

(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2014	**2013**	**2014**	**2013**
Revenue	$ 291	$ 338	$ 1,069	$ 490
Other revenues	-	-	-	300
Total revenue	291	338	1,069	790
Cost of goods sold	(81)	(78)	(291)	(464)
Gross profit	210	260	778	326
Selling, general and administrative	2,828	3,737	15,783	20,657
Research and development	667	2,049	4,299	12,688
Total operating expenses	3,495	5,786	20,082	33,345
Operating loss	(3,285)	(5,526)	(19,304)	(33,019)
Change in fair value of warrant liability, net	330	410	1,942	2,756
Interest income	1	2	5	20
Other expense and interest expense	9	322	(24)	(81)
Net loss	$ (2,945)	$ (4,792)	$ (17,381)	$ (30,324)
Common share data:				
Basic loss per common share*	$ (0.31)	$ (0.63)	$ (1.84)	$ (4.81)
Diluted loss per common share*	$ (0.31)	$ (0.63)	$ (1.84)	$ (5.10)
Weighted average number of basic common shares outstanding*	9,632,192	7,558,372	9,452,050	6,300,614
Weighted average number of diluted common shares outstanding*	9,632,192	7,558,372	9,452,050	6,569,011
Other comprehensive income (loss):				
Foreign currency translation adjustments	$ (70)	$ (325)	$ (76)	$ 59
Comprehensive loss	$ (3,015)	$ (5,117)	$ (17,457)	$ (30,265)

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

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

	December 31, 2014	**December 31, 2013**
Assets:		
Current assets		
Cash and cash equivalents	$ 20,469	$ 31,249
Accounts receivables, net	174	349
Inventories	349	719
Prepaid expenses and other current assets	974	1,711
Total current assets	21,966	34,028
Property, plant and equipment, net	1,798	3,069
Total assets	$ 23,764	$ 37,097
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$ 748	$ 582
Accrued expenses	3,603	3,740
Warrant liability	225	2,310
Total current liabilities	4,576	6,632
Other non-current liabilities	1,043	366
Total liabilities	5,619	6,998
Commitments and contingencies	—	—
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively	—	—

Common stock, $.01 par value; 170,000,000 shares authorized; 9,740,397 and 8,402,922 shares issued and 9,708,841 and 8,401,165 shares outstanding at December 31, 2014 and December 31, 2013, respectively *	97	84
Additional paid-in capital	264,592	259,102
Accumulated deficit	(246,513)	(229,132)
Treasury stock, at cost; 1,757 shares at December 31, 2014 and December 31, 2013, respectively	(51)	(51)
Accumulated other comprehensive income	20	96
Total stockholders' equity	18,145	30,099
Total liabilities and stockholders' equity	$ 23,764	$ 37,097

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

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