Delcath Announces Third Quarter Financial Results

November 11, 2016

NEW YORK, Nov. 11, 2016 /PRNewswire/ -- Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces financial results for the three and nine months ended September 30, 2016.

Highlights for the third quarter of 2016 and recent weeks include:

- Raised $1,275,000 through an underwritten public offering of common stock and warrants;
- Expanded the FOCUS Phase 3 Trial in hepatic dominant ocular melanoma to include 10 new research centers in the U.S. and Europe;
- Presented data from two single-institution studies conducted in Germany on the use of the Delcath Hepatic CHEMOSAT® Delivery System to treat patients with liver metastases in scientific posters at the *Cardiovascular and Interventional Radiology Society of Europe* (CIRSE) annual meeting;
- Announced acceptance for publication of a retrospective review study, "*Chemosaturation Percutaneous Hepatic Perfusion: A Systemic Review,*" by Dr. Arndt Vogel, et al, in the prestigious journal *Advances in Therapy;* and
- Sponsored the Ocular Melanoma Foundation *Eye Am Not Alone* patient education retreat.

"Throughout the third quarter we continued to make steady progress in our clinical development program for Melphalan/HDS and in our efforts to advance CHEMOSAT as a commercially viable treatment option for primary and metastatic liver cancers in Europe," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. "We also recently secured an additional $1.275 million in financing via a small fundraise in October, which will bridge us to receipt of the first cash release from the committed financing we announced in June 2016. Assuming all conditions are satisfied, we expect the anticipated quarterly releases throughout 2017 will fund our clinical development plan through the end of 2017, while also supporting our commercial activities in Europe.

"The presentation and publication of data supportive of CHEMOSAT continued during our third quarter. This includes a retrospective review study conducted by a team led by Dr. Arndt Vogel of the University of Hanover in Germany, which was accepted for publication by the prestigious peer-reviewed journal, *Advances in Therapy*. This study originated as a white paper produced by our Experts Panel in 2015, and we are pleased that the potential for CHEMOSAT to treat primary and metastatic liver cancers as identified by our experts will now reach a wider audience. Also during the quarter investigators from Asklepios Barmbek Clinic and Hanover Medical School in Germany, and Southampton University Hospital in the United Kingdom, presented compelling data from their single-institution investigations. These data provide us with considerable confidence that similar results may be formally validated by the trials that comprise our Clinical Development Plan, and we look forward to additional presentations and publications of data in support of CHEMOSAT throughout the remainder of the year and beyond.

"Negotiations by hospitals in Germany to determine reimbursement levels for CHEMOSAT under the ZE national system are expected to conclude during our fourth quarter. We believe that favorable reimbursement levels defined through this process will support growth in procedure volumes in Germany and provide important validation for reimbursement appeals in other markets in Europe.

"The advances we made in 2016 have positioned us to achieve important clinical inflection points in our FOCUS trial and our global Phase 2 program in HCC and ICC, as we work to expand global access to CHEMOSAT for the benefit of patients suffering with primary and metastatic liver cancers," concluded Dr. Simpson.

Third Quarter Financial Results

Total revenues for the third quarter of 2016 and 2015 were $0.4 million. Selling, general and administrative expenses for the third quarter of 2016 were $2.4 million, compared with $2.3 million for the same period in 2015, primarily attributable to a slight increase in facility and professional expenses. Research and development expenses increased to $2.7 million for the 2016 third

quarter from $1.7 million for the same period in 2015, primarily due to increased investment in clinical development initiatives, specifically the global Phase 3 FOCUS clinical trial.

Total operating expenses for the third quarter of 2016 increased to $5.0 million from $4.0 million for the same period in 2015. This reflects an increase in clinical development initiatives.

The Company recorded a net loss for the three months ended September 30, 2016 of $1.0 million, or $0.66 per share, a decrease of $1.4 million from a net loss of $2.4 million, or $1.96 per share, for the same period in 2015. This was primarily driven by amortization of debt discounts related to the convertible note issued in June 2016 and a change in the fair value of the warrant liability, a non-cash item.

Nine Month Financial Results

Total revenues for the first nine months of 2016 and 2015 were $1.3 million. Selling, general and administrative expenses for the first nine months of 2016 were $7.0 million, an improvement of $0.8 million or 11% from $7.8 million reported for the same period in 2015, primarily attributable to a reduction in facility expenses related to the lease restructurings. Research and development expenses during the first nine months of 2016 increased to $6.0 million compared with $4.1 million for the same period in 2015, primarily due to increased investment in clinical development initiatives.

Total operating expenses for the first nine months of 2016 were $13.0 million compared with $12.0 million for the same period in 2015.

The Company recorded a net loss for the nine months ended September 30, 2016 of $9.5 million, or $6.39 per share, a decrease of $0.1 million from a net loss of $9.6 million, or $10.75 per share, for the nine months ended September 30, 2015. This was primarily driven by amortization of debt discounts related to the convertible note issued in June 2016 and a change in the fair value of the warrant liability, a non-cash item.

Balance Sheet Highlights

As of September 30, 2016, Delcath had cash and cash equivalents of $3.7 million, compared with $12.6 million as of December 31, 2015. During the first nine months of 2016, the Company used $10.6 million in cash to fund its operating activities. In June 2016, Delcath issued $35.0 million of senior convertible notes and related common stock purchase warrants and in October 2016, the Company raised $1,275,000 through an underwritten public offering of common stock and warrants. As a result, Delcath believes it has sufficient capital to fund its operating activities through the end of 2017.

About Delcath Systems

Delcath Systems, Inc. is an interventional oncology Company focused on the treatment of primary and metastatic liver cancers. Our investigational 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 systemic exposure and associated side effects. We have commenced a global Phase 3 FOCUS clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) and a global Phase 2 clinical trial in Europe and the U.S. to investigate the Melphalan/HDS system for the treatment of primary liver cancer (HCC) and intrahepatic cholangiocarcinoma (ICC). Melphalan/HDS has not been approved by the U.S. Food & Drug Administration (FDA) for sale in the U.S. In Europe, our system has been commercially available since 2012 under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT), where it has been used at major medical centers to treat a wide range of cancers of 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: our ability to repay and comply with the obligations under our senior secured convertible notes, the timing and results of the Company's clinical trials including without limitation the OM, HCC ,and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma and the global Phase 2 HCC and ICC clinical trials, 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, if any, of publication of the Phase 3 trial manuscript to support the Company's efforts, the impact of the presentations at major medical conferences and future clinical results consistent with the data presented, the impact, if any of ZE reimbursement 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, the Company's ability to successfully commercialize the CHEMOSAT/Melphalan HDS system and the potential of the CHEMOSAT/Melphalan HDS 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 remaining 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 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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-Tables to Follow-

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenue	$ 435	$ 399	$ 1,316	$ 1,308
Cost of goods sold	112	90	373	360
Gross profit	323	309	943	948
Operating expenses:				
Selling, general and administrative	2,361	2,276	7,025	7,818
Research and development	2,686	1,683	5,975	4,112
Total operating expenses	5,047	3,959	13,000	11,930
Operating loss	(4,724)	(3,650)	(12,057)	(10,982)
Change in fair value of the warrant liability, net	8,680	1,253	9,171	1,414
Interest income (expense)	(4,963)	(14)	(6,584)	(39)
Other income (expense)	2	(11)	(15)	(4)
Net loss	$ (1,005)	$ (2,422)	$ (9,485)	$ (9,611)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(2)	(4)	(12)	(12)
Comprehensive loss	$ (1,007)	$ (2,426)	$ (9,497)	$ (9,623)
Common share data:				
Basic and diluted loss per common share*	$ (0.66)	$ (1.96)	$ (6.38)	$ (10.75)
Weighted average number of basic and diluted common shares outstanding*	1,521,927	1,233,086	1,486,986	893,819

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share data)

	September 30, 2016	December 31, 2015
	(Unaudited)	
Assets		
Current assets		
	$	$
Cash and cash equivalents	3,689	12,607
Restricted cash	23,737	—
Accounts receivables, net	342	277
Inventories	600	757

Prepaid expenses and other current assets	310	960
Deferred financing costs	489	—
Total current assets	29,167	14,601
Restricted cash, net of current portion	6,550	—
Deferred financing costs, net of current portion	122	—
Property, plant and equipment, net	1,141	1,132
Total assets	$ 36,980	$ 15,733
Liabilities and Stockholders' Equity		
Current liabilities		
	$	$
Accounts payable	182	284
Accrued expenses	2,701	2,243
Warrant liability	22,502	3,785
Total current liabilities	25,385	6,312
Convertible notes payable, net of debt discount	6,413	—
Deferred Revenue	31	—
Other non-current liabilities	665	820
Total liabilities	32,494	7,132
Commitments and Contingencies	—	—
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Common stock, $.01 par value; 500,000,000 shares authorized; 1,541,043 and 1,396,348 shares issued and 1,521,933 and 1,360,239 shares outstanding at September 30, 2016 and December 31, 2015, respectively*	15	14
Additional paid-in capital	275,245	269,863
Accumulated deficit	(270,703)	(261,217)
Treasury stock, at cost; 110 shares at September 30, 2016 and December 31, 2015, respectively*	(51)	(51)
Accumulated other comprehensive income	(20)	(8)
Total stockholders' equity	4,486	8,601
Total liabilities and stockholders' equity	$ 36,980	$ 15,733

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

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