Delcath Announces First Quarter 2017 Financial Results

NEW YORK, May 09, 2017 — 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 months ended March 31, 2017.

Highlights for the first quarter of 2017 and recent weeks include:

- First quarter 2017 revenue of $0.74 million, an increase of 100% compared with revenue of $0.37 million in prior year quarter;
- CHEMOSAT treatment milestone set by SPIRE Southampton Hospital in the U.K. with more than 100 CHEMOSAT treatments performed, including eight treatments on a single patient;
- Announced a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the design of a pivotal trial of Melphalan/HDS to treat patients with intrahepatic cholangiocarcinoma (ICC);
- The *American Journal of Clinical Oncology* published a single-center retrospective review finding that the Company's investigational percutaneous hepatic perfusion (PHP) with Melphalan/HDS offered promising results with a doubling of overall survival (OS), significantly longer progression-free survival (PFS) and hepatic progression-free survival (hPFS) compared with other targeted therapies; and
- Favorable data from two institutions were presented at the Regional Cancer Therapies Symposium and showed strong tumor response and overall survival with the Company's investigational PHP therapy in patients with ocular melanoma that metastasized to the liver.

"During the first three months of 2017 we continued to advance our clinical development programs in ocular melanoma liver metastases and intrahepatic cholangiocarcinoma, while making steady progress with commercialization of CHEMOSAT in Europe," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. "As we announced recently, we have concluded a new SPA agreement with the FDA for the initiation of a pivotal trial for the use of Melphalan/HDS in patients with ICC. This new trial will enroll approximately 295 ICC patients at about 40 clinical sites in the U.S. and Europe, with the primary endpoint of overall survival and with secondary and exploratory endpoints that include safety, progression-free survival, objective response rate and quality-of-life measures. The trial is designed to be cost-effective and conducted in a financially prudent manner, with modest investment in this fiscal year. In conjunction with the FOCUS Trial in ocular melanoma liver metastases, our clinical development programs now include two paths toward potential U.S. market approvals.

"In Europe, we continue to make steady progress with the commercialization of CHEMOSAT. Our first quarter revenue of more than $0.7 million was double the prior year period's sales, driven primarily by national reimbursement in Germany under the ZE system. With coverage

under the ZE system now in place, we expect product sales growth from this market for the remainder of 2017. Elsewhere in Europe, we continue to focus on building the clinical and pharmacoeconomic data to support reimbursement applications in other key markets. We expect that positive negotiations for coverage in Germany will support our efforts for payment levels in other markets such as the U.K. and the Netherlands. Securing reimbursement coverage in additional European markets remains critical to future revenue growth for CHEMOSAT," concluded Dr. Simpson.

First Quarter Financial Results

Revenue for the three months ended March 31, 2017 was $0.74 million, an increase of 100% from $0.37 million for the prior year period. Selling, general and administrative expenses were approximately $2.4 million, unchanged from the prior year quarter. Research and development expenses for the current quarter increased to $2.3 million from $1.3 million in the prior year quarter. Total operating expenses for the current quarter were $4.7 million compared with $3.7 million in the prior year quarter.

The Company reported a net loss for the 2017 first quarter of $11.3 million, or $0.25 per share based on 45.1 million weighted average common shares outstanding, compared with a net loss in the prior year period of $1.8 million or $1.25 per share based on 1.5 million weighted average common shares outstanding. The increase is primarily due to an $8.4 million increase in interest expense primarily related to the amortization of debt discounts, a non-cash item, and a $1.0 million increase in operating expenses primarily related to increased investment in clinical trial initiatives. This was offset by a $0.4 million change in the fair value of the warrant liability, a non-cash item, and a $0.27 million improvement in gross profit due to higher sales.

Balance Sheet Highlights

As of March 31, 2017, Delcath had cash and cash equivalents of $6.4 million, compared with $4.4 million as of December 31, 2016. During the first quarter of 2017, the Company used $3.8 million of cash to fund operating activities. Delcath believes it has sufficient capital and access to committed capital to fund its operating activities through the end of 2017.

Recent Financial Transactions

On April 2, 2017, Delcath entered into separate Warrant Repurchase Agreements with each of the investors named on the Schedule of Buyers attached to our Securities Purchase Agreement dated June 6, 2016. Pursuant to the Warrant Repurchase Agreements, each investor agreed to a Controlled Account Release in an aggregate amount equal to $7,876,312, which funds in each case were paid to the respective investor in exchange for cancellation of the Warrants issued to each investor under the Securities Purchase Agreement. Delcath anticipates that the cash remaining in the Controlled Accounts after this

transaction will be sufficient to fund 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 plan to initiate a Registration trial for intrahepatic cholangiocarcinoma (ICC) in the Fall of 2017. 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.

Forward Looking Statements:

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 OM and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 OM clinical trial, IRB or ethics committee clearance of the Phase 3 OM and ICC Registration trial protocols from participating sites and the timing of site activation and subject enrollment in each trial, the impact of the presentations at major medical conferences 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 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 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,, 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.

-Tables to Follow-

Delcath Systems, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share data)

	Year ended March 31,	
	2017	**2016**
Product revenue	$ 743	$ 370
Cost of goods sold	219	111
Gross profit	524	259
Operating expenses:		
Selling, general and administrative expenses	2,415	2,377
Research and development costs	2,321	1,344
Total operating expenses	4,736	3,721
Operating loss	(4,212)	(3,462)
Change in fair value of the warrant liability, net	1,238	1,672
Interest income (expense)	(8,366)	5
Other income (expense)	8	(28)
Net loss	$ (11,332)	$ (1,813)
Other comprehensive loss:		
Foreign currency translation adjustments	$ (22)	$ 8
Comprehensive Loss	$ (11,354)	$ (1,805)
Common share data:		
Basic and diluted loss per common share*	$ (0.25)	$ (1.25)
Weighted average number of basic and diluted shares outstanding*	45,084,357	1,455,544

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

DELCATH SYSTEMS, INC.
Consolidated Balance Sheets
as of March 31, 2017 and December 31, 2016
(in thousands, except share and per share data)

	March 31,	**December 31,**

	2017 (Unaudited)	2016
Assets		
Current assets		
Cash and cash equivalents	$ 6,404	$ 4,409
Restricted cash	20,737	27,287
Accounts receivables, net	386	403
Inventories	873	660
Prepaid expenses and other current assets	624	698
Deferred financing costs	949	699
Total current assets	29,973	34,156
Property, plant and equipment, net	1,066	1,083
Total assets	$ 31,039	$ 35,239
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 699	$ 594
Accrued expenses	3,548	3,407
Convertible notes payable, net of debt discount	9,290	13,343
Warrant liability	17,513	18,751
Total current liabilities	31,050	36,095
Deferred revenue	30	30
Other non-current liabilities	545	604
Total liabilities	31,625	36,729
Commitments and contingencies (Note 12)	–	
Stockholders' Equity (Deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	–	–
Common stock, $.01 par value; 500,000,000 shares authorized; 118,568,425 and 4,131,527 shares issued and 118,457,971 and 4,112,417 shares outstanding at March 31, 2017 and December 31, 2016, respectively*	1,186	41
Additional paid-in capital	288,862	277,749
Accumulated deficit	(290,520)	(279,188)
Treasury stock, at cost; 110 shares at March 31, 2017 and December 31, 2016, respectively*	(51)	(51)
Accumulated other comprehensive loss	(63)	(41)
Total stockholders' equity (deficit)	(586)	(1,490)
Total liabilities and stockholders' equity (deficit)	$ 31,039	$ 35,239

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

Contact Information:
David Boral
Managing Director
CoreIR
Tel: 516 222 2560
Email: davidb@coreir.com