Delcath Announces Second Quarter 2017 Financial Results

Company Comments on Consent Proposal; Provides Corporate Update

NEW YORK, Aug. 8, 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 and six months ended June 30, 2017.

Highlights from the second quarter of 2017 and recent weeks include:

- Revenue for the second quarter of 2017 increased 20% to $0.6 million from $0.5 million in the prior-year quarter;
- Revenue for the first six months of 2017 increased 44% to $1.3 million from $0.9 million in the prior-year period;
- Inclusion of CHEMOSAT in Dutch Health Authorities Guidelines (published in July 2017) as a recommended treatment for ocular melanoma liver metastases;
- Reduction of an additional $9.5 million in principal amount related to the Company's Convertible Notes, with $12.6 million in debt remaining; and
- Raised $2.0 million through the issuance of Series B preferred shares to current noteholders, which are convertible into common shares at $0.153 per share.

Proposal on Effecting a Reverse Stock Split

Delcath recently filed a Definitive Schedule 14A detailing a proposed reverse stock split, subject to shareholder approval. Delcath needs the ability to issue common shares to fund operations, support clinical programs, service the amortization of its Convertible Note and explore alternative equity financing opportunities. However, the Company is currently at the maximum amount of authorized shares of common stock under its Certificate of Incorporation. Without a significant increase in available authorized shares, the Company is unable to access the $11.8 million of cash in the restricted accounts associated with the Convertible Notes issued last year, or to undertake any type of equity financing. The proposed reverse stock split will reduce the number of shares outstanding and provide Delcath with the flexibility to raise equity capital and support its important clinical trials and commercial efforts in Europe.

In addition, the reverse stock split will allow Delcath to regain compliance with NASDAQ Capital Markets continued-listing requirements, which provides liquidity and other important benefits to the Company and its investors. It is important to note that the floor price for the Convertible Note will adjust with the effected reverse stock split ratio to a minimum of $1.00. Delcath believes this will serve to support the stock price following a split and reduce future potential dilution related to the Convertible Notes.

For these reasons, the Company's Board of Directors encourage all investors to support the

proposed reverse stock split. Investors are encouraged to read the Company's Definitive Schedule 14A in detail for full information regarding the proposed reverse stock split.

Management Commentary

"During the first half of 2017 we continued to advance our clinical development programs in ocular melanoma liver metastases (OM) and intrahepatic cholangiocarcinoma (ICC), while making steady progress with the ongoing commercialization of CHEMOSAT in Europe," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath.

"Revenues for the second quarter of 2017 increased 20% from a year ago, demonstrating continued growing demand in our core markets. This increase is largely driven by the recent establishment of ZE diagnostic-related (DRG) reimbursement for CHEMOSAT in Germany. We continue to leverage this positive German reimbursement to support our efforts to obtain market access and payment in other markets such as the U.K. and the Netherlands, where there is growing interest in and use of CHEMOSAT. This is evidenced by the recent inclusion of CHEMOSAT in the Dutch Health Authorities treatment guidelines for ocular melanoma liver metastases, an important step toward eventual reimbursement coverage of CHEMOSAT in the Dutch market.

"Our primary focus continues to be on the clinical trials that comprise our Clinical Development Program (CDP), where we believe shareholder value ultimately lies. Our CDP consists of our FOCUS Phase 3 clinical trial of Melphalan/HDS in hepatic dominant OM (the FOCUS trial) and our intrahepatic cholangiocarcinoma (ICC) pivotal trial, which is scheduled to initiate enrollment by the end of 2017. The objective for our Phase 2 trial program in hepatocellular carcinoma (HCC) and ICC was to identify an efficacy signal worthy of further clinical investigation. This objective was met by the retrospective data collection performed by European investigators last year, which informed our development path for ICC. The U.S. Food and Drug Administration (FDA) endorsed that development pathway via a Special Protocol Assessment agreement negotiated earlier this year. With the Phase 2 trial program goals now met, we have terminated enrollment in the Phase 2 trials in order to devote available resources to the FOCUS Trial and the Phase 3 ICC pivotal trial.

"In March, we announced a SPA with the FDA for a pivotal trial of our Melphalan/HDS to treat ICC. As with the FOCUS trial, this SPA indicates that the trial design adequately addresses objectives that, if met, will support regulatory requirements for approval of Melphalan/HDS in the treatment of ICC. Since announcing the SPA we have been working with potential trial sites with the goal of initiating patient enrollment by the end of 2017. We are committed to executing this trial in a financially prudent manner and for this reason initiation of enrollment is contingent on effecting the reverse stock split as outlined in our consent proposal.

Enrollment in our FOCUS Phase 3 clinical trial of Melphalan/HDS in hepatic dominant OM (the FOCUS trial) has been proceeding more slowly than we expected. We have been continually

reviewing the pace of recruitment in this study, and have discovered reluctance among some patients to participate as there was no mechanism to receive the experimental treatment at any time if they were randomized to the best alternative care arm. In a rare and deadly disease such as OM, it is not surprising that patients facing few treatment options would be reluctant to participate in a trial where there is no opportunity to receive the experimental treatment and where treatment is commercially available on a private pay basis in Europe. We are currently exploring options that will allow us to accelerate enrollment, which include adding new sites in both the U.S. and Europe. We have recently added several European clinical sites that are expected to provide increased patient flow starting this fall. We remain on track to conduct an interim safety analysis by the end of this year.

“Throughout the balance of 2017 we remain dedicated to advancing the clinical programs for our innovative Melphalan/HDS as well as to our commercialization efforts for CHEMOSAT in Europe. In order to support these important programs and create value, we need to enhance our capital structure, which begins with a favorable vote on the reverse stock split,” concluded Dr. Simpson.

Second Quarter Financial Results

Revenue for the second quarter of 2017 was $0.6 million, an increase of 20% from $0.5 million for the second quarter of 2016. Selling, general and administrative expenses increased modestly to $2.5 million in the 2017 second quarter from $2.3 million in the prior-year quarter. Research and development expenses for the second quarter of 2017 increased to $2.5 million from $1.9 million in the prior-year quarter. Total operating expenses for the current quarter were $5.0 million compared with $4.2 million in the prior-year quarter.

The Company recorded a net loss for the three months ended June 30, 2017, of $2.0 million, a decrease of $4.7 million, or 70.9%, compared to a net loss of $6.7 million for the same period in 2016. This decrease in net loss is primarily due to a $9.6 million gain on the extinguishment of the June 2016 Series C Warrants which was offset by a $5.3 million increase in interest expense related to the convertible note, both non-cash items. Additionally, there was a $1.2 million decrease in the change in the fair value of the warrant liability, a non-cash item, offset by a $0.8 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives.

Six Month Financial Results

Revenue for the first half of 2017 was $1.3 million, an increase of 44% from $0.9 million for the first half of 2016. Selling, general and administrative expenses in the first half of 2017 were approximately $4.9 million compared with $4.7 million in the prior-year period. Research and development expenses for the first six months of 2017 increased to $4.8 million from $3.3 million in the first six months of 2016. Total operating expenses for the first half of 2017 were $9.8 million compared with $8.0 million in the prior-year quarter.

The Company recorded a net loss for the six months ended June 30, 2017, of $13.3 million, an increase of $4.8 million, or 56.5%, compared to a net loss of $8.5 million for the same period in 2016. This increase in net loss is primarily due to a $13.7 million increase in interest expense primarily related to the amortization of debt discounts, offset by a $9.6 million gain on the extinguishment of the June 2016 Series C Warrants, both non-cash items. Additionally, there was a $1.8 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives, offset by $0.4 million increase in gross profit and a $0.7 million increase in the change in the fair value of the warrant liability, a non-cash item.

Balance Sheet Highlights

As of June 30, 2017, Delcath had cash and cash equivalents of $1.8 million, compared with $4.4 million as of December 31, 2016. In addition, the Company has $12.9 million in restricted cash primarily related to the Convertible Notes issued in June 2016. During the six months ended June 30, 2017, the Company used $8.1 million of cash to fund operating activities. Assuming the Company is able to effect a reverse stock split as proposed in its recent consent solicitation statement filed with the SEC on July 26, 2017, management believes that its capital resources are adequate to fund operating activities through the end of 2017.

Recent Financial Transactions

In July 2017 Delcath issued two series of preferred stock (Series A Preferred Stock and Series B Preferred Stock) in transactions with holders of its Convertible Note. The Series A shares were issued to address a short-term valuation issue for common shares delivered to the Note holders to close an installment period. Through the Series A Preferred Shares placement, the Company was able to value the open installment shares such that the amount of debt remaining under the Convertible Note was reduced by $4.2 million. The Series B Preferred Shares, which are convertible to common shares at $0.153, allowed the Company to raise $2.0 million in unrestricted cash.

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.

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-Tables to Follow-

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

	Three months ended June 30,		Six months ended June 30,	
	2017	**2016**	**2017**	**2016**
Product revenue	$ 584	$ 511	$ 1,327	$ 880
Cost of goods sold	135	150	354	261
Gross profit	449	361	973	619
Operating expenses:				
Selling, general and administrative expenses	2,532	2,287	4,947	4,663
Research and development costs	2,518	1,945	4,840	3,289
Total operating expenses	5,050	4,232	9,787	7,952
Operating loss	(4,601)	(3,871)	(8,814)	(7,333)
Change in fair value of the warrant liability, net	(38)	(1,181)	1,200	491
Gain on warrant extinguishment	9,613	–	9,613	–
Interest income (expense)	(6,916)	(1,614)	(15,282)	(1,631)
Other income (expense)	(1)	(1)	7	(7)
Net loss	$ (1,943)	$ (6,667)	$ (13,276)	$ (8,480)
Other comprehensive loss:				
Foreign currency translation adjustments	$ (30)	$ (1)	$ (8)	$ (10)
Comprehensive Loss	$ (1,973)	$ (6,668)	$ (13,284)	$ (8,490)
Common share data:				
Basic loss per share*	$ (0.01)	$ (4.41)	$ (0.09)	$ (5.72)
Diluted loss per share*	$ (0.01)	$ (4.41)	$ (0.09)	$ (5.72)
Weighted average number of basic common shares outstanding*	252,264,959	1,510,752	148,674,658	1,483,148

Weighted average number of diluted common shares outstanding*	252,264,959	1,510,752	148,722,094	1,483,148

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

DELCATH SYSTEMS, INC.

Consolidated Balance Sheets

as of June 30, 2017 and December 31, 2016

(in thousands, except share and per share data)

	June 30, 2017 (Unaudited)	**December 31, 2016**
Assets		
Current assets		
Cash and cash equivalents	$ 1,816	$ 4,409
Restricted cash	12,861	27,287
Accounts receivables, net	384	403
Inventories	1,040	660
Prepaid expenses and other current assets	499	698
Deferred financing costs	771	699
Total current assets	17,371	34,156
Property, plant and equipment, net	1,232	1,083
Total assets	$ 18,603	$ 35,239
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 990	$ 594
Accrued expenses	3,579	3,407
Convertible notes payable, net of debt discount	12,598	13,343
Warrant liability	43	18,751
Total current liabilities	17,210	36,095
Deferred revenue	32	30
Other non-current liabilities	494	604
Total liabilities	17,736	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 June 30, 2017 and December 31, 2016, respectively	–	–
Common stock, $.01 par value; 500,000,000 shares authorized; 424,526,067 and 4,131,527 shares issued and 424,408,256 and 4,112,417 shares outstanding at June 30, 2017 and December 31, 2016, respectively*	4,245	41
Additional paid-in capital	289,186	277,749
Accumulated deficit	(292,464)	(279,188)
Treasury stock, at cost; 110 shares at June 30, 2017 and December 31, 2016, respectively*	(51)	(51)
Accumulated other comprehensive loss	(49)	(41)
Total stockholders' equity (deficit)	867	(1,490)
Total liabilities and stockholders' equity (deficit)	$ 18,603	$ 35,239

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

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