Delcath Announces First Quarter 2018 Financial Results

NEW YORK, May 10, 2018 — Delcath Systems, Inc. (OTCQB:DCTHD), an interventional oncology Company focused on the treatment of primary and metastatic liver cancers, announces financial results for the quarter ended March 31, 2018.

Highlights from the first quarter of 2018 and recent weeks include:

- Revenue from European sales for the quarter was $0.7 million;
- Completed a $5.0 million capital raise in February 2018;
- Announced that the independent Data Safety Monitoring Board (DSMB) of the Phase 3 FOCUS clinical trial has again recommended that the study continue without modification;
- Announced the opening of the ALIGN registration trial for the treatment of Intrahepatic Cholangiocarcinoma (ICC);
- Modified the Special Protocol Agreement (SPA) with the U.S. Food and Drug Administration (FDA) for the Company's Phase 3 clinical trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) to treat patients with hepatic dominant ocular melanoma (OM);
- CHEMOSAT featured in main stage training presentation at European Conference on Interventional Oncology;
- Reported the 500th CHEMOSAT treatment in Europe;
- Announced results from a multi-center analysis of Delcath's Percutaneous Hepatic Perfusion (PHP) therapy in the peer-reviewed *Journal of Surgical Oncology*; largest data set outside of clinical trial showed manageable toxicity and overall median overall survival of 15.3 months; and
- Secured a commercial supply of melphalan hydrochloride for injection through an agreement with Tillomed Laboratories

Management Commentary

"Our focus continues to be on resolving the cash constraints and other restrictions related to our capital structure," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. "These limitations have necessitated the series of transactions we completed in second half of 2017 and the early weeks of 2018, permitting us to exit our 2016 Convertible Note, raise additional capital, invest in our clinical development program, and advance our commercialization efforts for CHEMOSAT in Europe. We continue to work to resolve the remaining issues and secure new equity financing in order to execute our plan and create value for our shareholders."

"Despite cash constraints, revenues for the first quarter of 2018 were $0.7 million, consistent with the prior year quarter and reflecting steady adoption of CHEMOSAT in our core European

markets. During the quarter, we announced a commercial supply agreement with Tillomed Laboratories for the supply of melphalan hydrochloride. This agreement provides us with firm control over our melphalan supply chain in Europe and, over time, will provide economies of scale. The supply agreement with Tillomed also gives Delcath access to the drug dossier for melphalan hydrochloride, an important asset that potentially provides a drug approval pathway with the European Medicines Agency (EMA) in Europe. As many of the cancers of the liver we are treating with CHEMOSAT are orphan indications in the United States, a Marketing Authorization Application (MAA) approval by the EMA for CHEMOSAT could potentially provide added market protection for these indications in Europe.

"Regarding our FOCUS Phase 3 Trial, we recently announced that the independent Data Safety Monitoring Board (DSMB) has completed another review of safety data for treated patients in the trial, and has again recommended that the study continue without modification. Enrollment in this trial remains slower than projected, and our ability to take proactive steps to support enrollment continues to be limited by the cash constraints we have been operating under. We continue to rollout the SPA protocol modification we announced in January to participating centers, and hope to accelerate enrollment in 2018 once cash constraints are alleviated. Any impact on enrollment from the SPA modification is not expected to be immediate, and it is unlikely that enrollment for this trial will be completed in time to submit an NDA to the FDA in 2019. We plan to update our enrollment projections in the second half of this year.

"On May 7, 2018 we announced the initiation our registration trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) to treat patients with intrahepatic cholangiocarcinoma (ICC). Called The ALIGN Trial, this trial will seek to enroll approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe. The trial is being conducted under a Special Protocol Assessment (SPA) agreement reached with the U.S. Food and Drug Administration (FDA) in March 2017. The ALIGN Trial is based on a strong efficacy signal observed in the ICC tumor type through our commercial experience with CHEMOSAT in Europe. The sequential design of the therapies under investigation in the trial will allow us to minimize capital investment requirements in 2018. We are also leveraging our existing network of trial sites from our FOCUS Phase 3 trial to rollout the trial protocol as efficiently as possible. In this orphan population where there exists a huge unmet need, this trial provides us with a second pathway to commercial drug approval in the United States, and if successful we believe will be an important value driver for the Company.

"Though the recent months have been financially difficult, we remain committed to advancing our clinical and commercial programs. We are continuously working to improve our ability to operate so we can realize the potential of PHP therapy and return value to our shareholders," concluded Dr. Simpson.

First Quarter 2018 Financial Results

Revenue for the three months ended March 31, 2018 was $0.7 million, a slight decrease from $0.74 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 $5.7 million from $2.3 million in the prior year quarter. Total operating expenses for the current quarter were $8.1 million compared with $4.7 million in the prior year quarter.

The Company recorded net income for the three months ended March 31, 2018, of $7.2 million, an increase of $18.5 million, or 163.4%, compared to a net loss of $11.3 million for the same period in 2017. This increase in net income is primarily due to an $8.3 million decrease in interest expense primarily related to the amortization of debt discounts related to convertible notes that were fully satisfied in 2017, and a $13.5 million increase in the change in the fair value of the warrant liability, both non-cash items. Additionally, there was a $3.3 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives.

Balance Sheet Highlights

As of March 31, 2018, Delcath had cash and cash equivalents of $2.0 million, compared with $4.0 million as of December 31, 2017. During the first quarter, the Company used $6.4 million of cash to fund operating activities.

In February 2018, the Company completed the sale of 424,000 shares of its common stock and the issuance of warrants to purchase 1.0 million common shares (the “February 2018 Warrants”) pursuant to a placement agent agreement. The Company received net proceeds of $4.6 million, with cash proceeds after related expenses from this transaction of $4.3 million.

On April 9, 2018 the Company announced that shareholders approved the provisions of the Company’s Consent Solicitation filed with the Securities Exchange Commission (SEC) on February, 26, 2018. By a vote of 54.3%, shareholders as of the record date of February 9, 2018 approved the Company’s proposals to amend its certificate of incorporation to increase its authorized shares of common stock from 500,000,000 to 1,000,000,000 (the Authorized Share Increase), and, by a vote of 52.8%, to effect a reverse stock split of the Company’s common stock at a range of 1-for-100 to 1-for-500 (the Reverse Stock Split Authorization). We effected our increase in authorized shares on April 21, 2018 and our 1-for-500 reverse stock split on May 2, 2018.

Delcath believes it has sufficient capital and access to committed capital to fund its operating activities through May of 2018.

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 have initiated a Registration trial for intrahepatic cholangiocarcinoma (ICC) called The ALIGN Trial. 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, 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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–Financial Tables to Follow–

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

	Three months ended March 31,	
	2018	**2017**
Revenue	$ 702	$ 743
Cost of goods sold	147	219
Gross profit	555	524
Operating expenses:		
Selling, general and administrative	2,366	2,415
Research and development	5,692	2,321
Total operating expenses	8,058	4,736
Operating loss	(7,503)	(4,212)
Change in fair value of the warrant liability, net	14,697	1,238
Interest expense	(2)	(8,366)
Other (expense) income	(5)	8
Net income (loss)	$ 7,187	$ (11,332)
Other comprehensive income (loss):		
Foreign currency translation adjustments	(34)	(22)
Comprehensive income (loss)	$ 7,153	$ (11,354)
Common share data:		
Basic income (loss) per common share*	$ 10.91	$ (45,695)
Diluted income (loss) per share*	$ 10.91	$ (45,695)
Weighted average number of basic shares outstanding*	658,893	248
Weighted average number of diluted shares outstanding*	658,893	248

*reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.

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

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 2,029	$ 3,999
Restricted cash	1,087	1,325
Accounts receivables, net	280	317
Inventories	1,280	1,248
Prepaid expenses and other current assets	554	700
Total current assets	5,230	7,589
Property, plant and equipment, net	1,188	1,298
Total assets	$ 6,418	$ 8,887
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 4,580	$ 3,846
Accrued expenses	3,526	3,408
Warrant liability	4,169	560
Total current liabilities	12,275	7,814
Other non-current liabilities	345	395
Total liabilities	12,620	8,209
Commitments and Contingencies	–	–
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	–	–
Common stock, $.01 par value; 500,000,000 shares authorized; 896,995 and 228,140 shares issued and 896,994 and 228,139 shares outstanding at March 31, 2018 and December 31, 2017, respectively*	9	2
Additional paid-in capital	311,477	325,517
Accumulated deficit	(317,645)	(324,832)
Treasury stock, at cost; 1 share at March 31, 2018 and December 31, 2017, respectively*	(51)	(51)
Accumulated other comprehensive income	8	42
Total stockholders' (deficit) equity	(6,202)	678
Total liabilities and stockholders' equity	$ 6,418	$ 8,887

*reflects a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017 and a one-for-five hundred (1:500) reverse stock split effected on May 2, 2018.