Delcath Announces Third Quarter Fiscal 2018 Financial Results

NEW YORK, Nov. 13, 2018 — Delcath Systems, Inc. (OTCQB: DCTH), an interventional oncology company focused on the treatment of primary and metastatic liver cancers, announces financial results for the quarter ended September 30, 2018.

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

- First patients treated in the Company's amended Phase 3 clinical trial in ocular melanoma liver metastases (the FOCUS Trial)
- Raised $7.0 million in net proceeds from the September 2018 rights offering
- Revenue from European sales for the quarter of approximately $0.8 million and $2.4 million for the first nine months of 2018, an increase of approximately 20% over the first nine-months of 2017
- First patient treated in global Phase 3 clinical trial for intrahepatic cholangiocarcinoma (ICC) (the ALIGN Trial)
- Publication of ICC outcomes data in *European Radiology*
- Positive results from prospective and retrospective studies on CHEMOSAT presented at 2018 CIRSE annual conference
- 3rd Data Safety Monitoring Board (DSMB) of the Phase 3 FOCUS clinical trial has again recommended that the study continue without modification;

Management Commentary

"Our third quarter was a productive period for Delcath during which we took major steps to advance our Clinical Development Program while working to resolve the cash constraints and other restrictions that have impeded our ability to operate," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath.

"During the quarter, we began aggressively rolling out the amended protocol for our FOCUS registration trial in ocular melanoma liver metastases, activating centers in both the United States and Europe and treating the first patients under the new single arm protocol. We continue to work toward our goal of completing enrollment in this trial by the end of the first half of 2019."

"In October, we announced treatment of the first patient in our registration trial of Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS) to treat patients with ICC (the ALIGN Trial.) The ALIGN Trial is based on a positive efficacy signal observed in a multi-center analysis in the ICC tumor type with CHEMOSAT in Europe, which were published in European Radiology. In this orphan population where there exists an unmet medical 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."

"During our third quarter we also completed our September 2018 Rights Offering, through which we secured approximately $7.2 million in net proceeds. Though the Rights Offering provided the capital that allowed us to advance our plans during the quarter, it fell short of our expectations. We will require and continue to seek additional capital to complete the clinical trials on which shareholder value ultimately depends."

"Though we still face many challenges, we have taken significant steps to advance our clinical and commercial programs and to obtain the financial resources required to realize PHP therapy's potential," concluded Dr. Simpson.

Third Quarter 2018 Financial Results

Revenue for the three months ended September 30, 2018 was $0.8 million, up from $0.7 million for the prior year period driven by the establishment of reimbursement coverage of CHEMOSAT procedures in Germany. Selling, general and administrative expenses were approximately $2.3 million compared to $2.9 million in the prior year quarter, a decrease related to costs associated with the Company's shareholder meetings held in 2017 that were not incurred in 2018, and a reduction in independent audit fees incurred in 2017 that were not required in 2018. Research and development expenses for the current quarter increased to $4.1 million from $2.3 million in the prior year quarter, driven by increase costs associated primarily due to the ongoing accrual of the Company's Phase 3 FOCUS trial. Total operating expenses for the current quarter were $6.4 million compared with $5.1 million in the prior year quarter.

The Company recorded a net loss for the three months ended September 30, 2018, of $8.9 million, a decrease of $3.7 million, or 29.5%, compared to a net loss of $12.6 million for the same period in 2017. This decrease in net loss is primarily due to a $1.9 million decrease in interest expense, a $1.8 million reduction in loss on debt extinguishment and a $1.2 million increase in the change in the fair value of the warrant liability, all non-cash items. This decrease was slightly offset by a $1.2 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives.

Balance Sheet Highlights

At September 30, 2018, the Company had cash, cash equivalents and restricted cash totaling $10.0 million, as compared to cash, cash equivalents and restricted cash totaling $5.3 million at December 31, 2017 and $10.9 million at September 30, 2017. During the nine months ended September 30, 2018 and September 30, 2017, the Company used $12.9 million and $11.7 million respectively, of cash in its operating activities. Including the $850,000 raised in November 2018 through the issuance of Series D Preferred Shares, the Company believes that its capital resources are adequate to fund its operating activities into December 2018.

September 2018 Rights Offering

In September 2018, the Company completed the sale of 4,667,811 shares of its common stock, with net proceeds after expenses of approximately $7.0 million.

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 been enrolling a global Registration clinical trial for Patients with Hepatic Dominant Ocular Melanoma (OM) called The FOCUS Trial and have initiated a global Phase 3 clinical 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

The 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 and ICC clinical trials, 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.

Contact:
Delcath Investor Relations
Email: investorrelations@delcath.com

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,	
	2018	**2017**	**2018**	**2017**
Revenue	$ 824	$ 684	$ 2,384	$ 2,011
Cost of goods sold	233	172	600	527
Gross profit	591	512	1,784	1,484
Operating expenses:				
Selling, general and administrative	2,279	2,860	7,286	7,807
Research and development	4,106	2,279	13,886	7,119
Total operating expenses	6,385	5,139	21,172	14,926
Operating loss	(5,794)	(4,627)	(19,388)	(13,442)
Change in fair value of the warrant liability, net	1,198	27	18,407	1,227
Gain on warrant extinguishment	–	–	–	9,613
Loss on debt extinguishment	(1,123)	(2,952)	(1,123)	(2,952)
Loss on issuance of financial instrument	–	–	(2,826)	–
Interest expense	(3,151)	(5,042)	(3,402)	(20,324)
Other (expense) income	(10)	(2)	(21)	5
Net loss	$ (8,880)	$ (12,596)	$ (8,353)	$ (25,873)
Other comprehensive loss:				
Foreign currency translation adjustments	105	(15)	63	7
Comprehensive loss	$ (8,775)	$ (12,611)	$ (8,290)	$ (25,866)

Common share data:				
Basic loss per common share*	$ (0.25)	$ (4,565)	$ (0.60)	$ (17,313)
Diluted loss per common share*	$ (0.25)	$ (4,565)	$ (0.64)	$ (17,313)
Weighted average number of basic shares outstanding*	35,859,866	2,763	13,888,577	1,494
Weighted average number of diluted shares outstanding*	35,859,866	2,763	13,888,587	1,494

*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)

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 8,913	$ 3,999
Restricted cash	1,062	1,325
Accounts receivables, net	364	317
Inventories	954	1,248
Prepaid expenses and other current assets	527	700
Total current assets	11,820	7,589
Property, plant and equipment, net	1,012	1,298
Total assets	$ 12,832	$ 8,887
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 6,783	$ 3,846
Accrued expenses	6,125	3,408
Current portion of convertible notes payable, net of debt discount	2,664	–
Warrant liability	1,475	560
Total current liabilities	17,047	7,814
Convertible notes payable, net of current portion and debt discount	116	–
Other non-current liabilities	534	395
Total liabilities	17,697	8,209

Commitments and Contingencies	–	–
Stockholders' (deficit) equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	–	–
Common stock, $.01 par value; 1,000,000,000 shares authorized; 5,694,437 and 263,275 shares issued and 5,694,436 and 263,274 shares outstanding at September 30, 2018 and December 31, 2017, respectively*	57	3
Additional paid-in capital	328,209	325,516
Accumulated deficit	(333,185)	(324,832)
Treasury stock, at cost; 1 share at September 30, 2018 and December 31, 2017, respectively*	(51)	(51)
Accumulated other comprehensive income	105	42
Total stockholders' (deficit) equity	(4,865)	678
Total liabilities and stockholders' equity	$ 12,832	$ 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.