Delcath Announces Second Quarter Fiscal 2018 Financial Results

August 15, 2018

NEW YORK, Aug. 15, 2018 (GLOBE NEWSWIRE) -- **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 June 30, 2018.

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

- Amendment of the Company's ongoing Phase 3 clinical trial in ocular melanoma liver metastases to a non-randomized, single-arm trial
- Initiation of a $50 million rights offering
- Revenue from European sales for the quarter of approximately $0.9 million;
- 100th CHEMOSAT treatment performed at Leiden University Medical Center;
- Inclusion of CHEMOSAT in the German national treatment guidelines for liver metastases from melanoma.
- Announcement that the independent Data Safety Monitoring Board (DSMB) of the Phase 3 FOCUS clinical trial has again recommended that the study continue without modification;
- Initiation of the ALIGN registration trial for the treatment of Intrahepatic Cholangiocarcinoma (ICC);
- CHEMOSAT featured in main stage training presentation at European Conference on Interventional Oncology;

Management Commentary

"During our second quarter we continued to advance the major elements of our Clinical Development Program while taking steps to resolve the cash constraints and other restrictions that have impeded our ability to operate in recent weeks," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. "These efforts culminated with the announcements we made in July of the protocol amendment to our ongoing FOCUS Phase 3 trial in ocular melanoma liver metastases to permit a non-randomized single-arm study, and our $50 million rights offering. These are highly significant developments for Delcath, and together provide both a path toward an application for FDA approval and the necessary financing to achieve it."

"Revenues for the second quarter of 2018 were approximately $0.9 million, an increase of nearly 50% over approximately $0.6 million in the prior year quarter. During the quarter, we announced CHEMOSAT was included in the German national treatment guidelines for ocular melanoma liver metastases, and that our third European commercial treatment center achieved the 100-treatment milestone. To date centers in Europe have completed over 600 CHEMOSAT treatments. CHEMOSAT was also featured in a main state presentation at the ECIO annual meeting, demonstrating the continued interest in the European research community in PHP therapy's potential.

"Regarding our FOCUS Phase 3 Trial, in addition to the protocol amendment we announced in May that the independent Data Safety Monitoring Board (DSMB) has completed another review of safety data for treated patients in the trial and again recommended that the study continue without safety related modification. Safety data for the amended trial will be pooled with all patients treated with Melphalan/HDS under the prior protocol.

"During the second quarter, we announced the initiation of 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. We are leveraging our existing network of trial sites from our FOCUS Phase 3 trial to rollout the trial protocol as efficiently as possible and have 3 centers open for patient enrollment to date. 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 difficult we have taken significant steps to reduce our time to NDA submission, advance our clinical and commercial programs, and obtain the financial resources required to realize PHP therapy's potential and return value to our shareholders," concluded Dr. Simpson.

Second Quarter 2018 Financial Results

Revenue for the three months ended June 30, 2018 was $0.9 million, up from $0.6 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 $2.6 million compared to $2.5 million in the prior year quarter, a slight increase related to decreased production and adjustments to overhead allocations. Research and development expenses for the current quarter increased to $4.1 million from $2.5 million in the prior year quarter, driven by increased costs associated primarily due to the ongoing accrual of the Company's Phase 3 FOCUS trial. Total operating expenses for the current quarter were $6.7 million compared with $5.1 million in the prior year quarter.

The Company recorded net loss for the three months ended June 30, 2018, of $6.7 million, an increase of $4.7 million, or 242.6%, compared to a net loss of $1.9 million for the same period in 2017. This increase in net loss is primarily due to a $6.7 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 $2.6 million increase in the change in the fair value of the warrant liability, both non-cash items. Additionally, there was a $1.7 million increase in operating expenses primarily related to increased investment in our clinical trial initiatives.

Balance Sheet Highlights

At June 30, 2018, the Company had cash and cash equivalents totaling $1.3 million, as compared to cash and cash equivalents totaling $4.0 million at December 31, 2017 and $1.8 million at June 30, 2017. During the six months ended June 30, 2018 and June 30, 2017, the Company used $9.3 million and $8.1 million respectively, of cash in its operating activities. The Company believes that its capital resources are adequate to fund its operating activities through August 2018.

On June 4, 2018, the Company entered into a Securities Purchase Agreement (the "SPA") with an institutional investor pursuant to which the Company issued $3.3 million in principal face amount of senior secured convertible notes of the Company (the "Notes") and related Series D Warrants (the "Series D Warrants") to purchase additional shares of the Company's common stock ("Common Stock"). $3.3 million of the Notes were issued for cash proceeds of $2.4 million with an original issue discount in the amount of $1.1 million.

On July 20, 2018, the Company entered into a Securities Purchase Agreement with another institutional investor for the remaining Notes and Warrants in proportionate amounts to those issued in the June 4, 2018 transaction which is discussed in Note 7, in a transaction exempt from registration pursuant to Section 4(a)(2) of the Securities Act and Rule 506(b) promulgated thereunder, and received gross proceeds of $1,600,000.

Rights Offering & Bridge Financing

On July 16, 2018 the Company filed a registration statement on Form S-1 with the SEC for a rights offering for up to 28,571,429 shares of common stock at the subscription price of $1.75 per share. The subscription period this rights offering began on Tuesday, August 7, 2018 upon declaration of effectiveness of its registration statement on Form S-1 by the SEC.

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 called The ALIGN Trial for 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.

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: successful completion of the Company's Rights Offering and related transactions and the amount of gross proceeds, if any; 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. Except as required by federal securities law, 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 June 30,		Six months ended June 30,	
	2018	2017	2018	2017
Revenue	$ 858	$ 584	$ 1,560	$ 1,327
Cost of goods sold	220	135	367	354
Gross profit	638	449	1,193	973
Operating expenses:				
Selling, general and administrative	2,641	2,532	5,007	4,947
Research and development	4,089	2,518	9,781	4,840
Total operating expenses	6,730	5,050	14,788	9,787
Operating loss	(6,092)	(4,601)	(13,595)	(8,814)
Change in fair value of the warrant liability, net	2,513	(38)	17,209	1,200
Gain on warrant extinguishment	—	9,613	—	9,613
Loss on issuance of financial instrument	(2,826)	—	(2,826)	—
Interest expense	(248)	(6,916)	(251)	(15,282)
Other (expense) income	(5)	(1)	(10)	7
Net income (loss)	$ (6,658)	$ (1,943)	$ 527	$ (13,276)
Other comprehensive loss:				
Foreign currency translation adjustments	(36)	(30)	(78)	(8)
Comprehensive loss	$ (6,694)	$ (1,973)	$ 449	$ (13,284)
Common share data:				
Basic loss per common share*	$ (7.26)	$ (1,373)	$ 0.67	$ (15,656)
Diluted loss per common share*	$ (7.26)	$ (1,373)	$ (0.12)	$ (15,656)
Weighted average number of basic shares outstanding*	916,706	1,416	788,512	848
Weighted average number of diluted shares outstanding*	916,706	1,416	799,430	848

*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.

See accompanying notes to condensed financial statements.

DELCATH SYSTEMS, INC.

(in thousands, except share data)

	June 30, 2018 (Unaudited)	December 31, 2017
Condensed Consolidated Balance Sheets		
Current assets		
Cash and cash equivalents	$ 1,283	$ 3,999
Restricted cash	1,062	1,325
Accounts receivables, net	397	317
Inventories	1,250	1,248
Prepaid expenses and other current assets	382	700
Total current assets	4,374	7,589
Property, plant and equipment, net	1,099	1,298
Total assets	$ 5,473	$ 8,887
Liabilities and Stockholders' Deficit		
Current liabilities		

Accounts payable	$ 5,607	$ 3,846
Accrued expenses	5,220	3,408
Current portion of convertible notes payable, net of discount	387	—
Warrant liability	6,883	560
Total current liabilities	18,097	7,814
Convertible notes payable, net of current portion and debt discount	27	—
Other non-current liabilities	439	395
Total liabilities	18,563	8,209
Commitments and Contingencies	—	—
Stockholders' equity (deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Common stock, $.01 par value; 1,000,000,000 shares authorized; 932,159 and 263,305 shares issued and 932,158 and 263,304 shares outstanding at June 30, 2018 and December 31, 2017, respectively*	9	3
Additional paid-in capital	311,293	325,516
Accumulated deficit	(324,305)	(324,832)
Treasury stock, at cost; 1 share at June 30, 2018 and December 31, 2017, respectively*	(51)	(51)
Accumulated other comprehensive (loss) income	(36)	42
Total stockholders' (deficit) equity	(13,090)	678
Total liabilities and stockholders' equity	$ 5,473	$ 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.

See accompanying notes to condensed financial statements.