Delcath Announces Third Quarter 2017 Financial Results

November 14, 2017

NEW YORK, Nov. 14, 2017 (GLOBE NEWSWIRE) -- Delcath Systems, Inc. (OTCQB:DCTHD), an interventional oncology Company focused on the treatment of primary and metastatic liver cancers, announces financial results for the three and nine months ended September 30, 2017.

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

- Revenue for the third quarter of 2017 increased 75% to $0.7 million from $0.4 million in the prior-year quarter;
- Revenue for the first nine months of 2017 increased 53% to $2.0 million from $1.3 million in the prior-year period;
- Medical University of Hannover achieved its 100th CHEMOSAT treatment milestone; over 450 commercial CHEMOSAT procedures have been performed in Europe;
- Positive results from a single institution study of CHEMOSAT filtration efficiency were presented at 2017 CIRSE annual meeting in September; and
- Reverse stock split effected at ratio of 1:350 on November 6, 2017.

Management Commentary

"During our third quarter, we focused on resolving the cash constraints and other restrictions related to our authorized shares limit, which necessitated the reverse stock split we effected on November 6, 2017. The authorized share limit prevented the Company from accessing the restricted cash otherwise available under our 2016 convertible notes. With the ability to issues shares now restored, we are able to access the balance of the restricted cash and begin exploring opportunities for new equity financing necessary to execute on our Clinical Development Program (CDP) and European commercialization," said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath.

"Despite the cash constraints, revenues for the third quarter of 2017 increased 75% over the prior year quarter, continuing the steady growth in our core European markets. This growth was supported by the establishment of ZE diagnostic-related (DRG) reimbursement for CHEMOSAT in Germany last year, which we are leveraging to obtain market access and reimbursement in other regions such as the United Kingdom and the Netherlands. In the Netherlands, Dutch Health Authorities have included CHEMOSAT treatment in their published guidelines for ocular melanoma liver metastases, an important step toward eventual reimbursement coverage of CHEMOSAT in the Dutch market. During the quarter, Medical University of Hannover performed their 100th treatment since beginning CHEMOSAT procedures in 2014, the second of our Europe centers to have achieved this milestone. Since launching CHEMOSAT in Europe, over 450 commercial CHEMOSAT procedures have been performed.

"In our Clinical Development Program (CDP), our primary focus continues to be on our FOCUS Phase 3 clinical trial of Melphalan/HDS in hepatic dominant ocular melanoma (the FOCUS trial). Enrollment in this trial has been proceeding more slowly than anticipated, and cash constraints during the quarter limited our ability to take steps to accelerate enrollment. With the reverse split

effected we are exploring steps to accelerate enrollment, and will seek to add new trial sites in both the U.S. and Europe once new equity financing is secured. We still expect to conduct an interim safety analysis by the end of this year.

"For our pivotal trial in intrahepatic cholangiocarcinoma (ICC), we continue to work with potential trial sites with a view to initiating enrollment when financial resources permit. Our ICC pivotal trial is based on the prior work done in our Phase 2 trial program in hepatocellular carcinoma (HCC) and ICC, which had the objective of identifying 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. With the Phase 2 trial program goals now met, we have closed enrollment in the Phase 2 trials to devote available resources to the FOCUS Trial and the ICC pivotal trial.

"Though the recent months have been financially difficult, we remain committed to advancing the clinical programs for our innovative Melphalan/HDS as well as to our commercialization efforts for CHEMOSAT in Europe. We are continuously working to advance our ability to operate so we can advance these important programs to increase value to our shareholders," concluded Dr. Simpson.

Three Month Financial Results

Revenue for the third quarter of 2017 was $0.7 million, an increase of 75% from $0.4 million for the third quarter of 2016. Selling, general and administrative expenses increased modestly to $2.9 million in the 2017 third quarter from $2.4 million in the prior-year third quarter. Research and development expenses for the third quarter of 2017 declined slightly to $2.3 million from $2.7 million in the prior-year quarter. Total operating expenses for the current quarter were $5.1 million compared with $5.0 million in the prior-year quarter.

The Company reported a net loss for the 2017 third quarter of $12.6 million, or $9.36 per share based on 1.4 million weighted average common shares outstanding on a split adjusted basis. This compares with a net loss in the prior-year period of $1.0 million, or $230.99 per share based on 4,349 weighted average common shares outstanding on a split adjusted basis. This increase in net loss is primarily due to an $8.7 million change in the fair value of the warrant liability and a $3.0 million loss related to two transactions to settle convertible note debt, both non-cash items.

Nine Month Financial Results

Revenue for the first nine months of 2017 was $2.0 million, an increase of 53% from $1.3 million for the first nine months of 2016. Selling, general and administrative expenses in the first nine months 2017 were approximately $7.8 million compared with $7.0 million in the prior-year period. Research and development expenses for the first nine months of 2017 increased to $7.1 million from $6.0 million in the first nine months of 2016. Total operating expenses for the first nine months of 2017 were approximately $15.0 million compared with $13.0 million in the prior-year quarter.

The Company recorded a net loss of $25.8 million for the first nine months of 2017, or $34.99 per share based on 754,421 weighted average common shares outstanding on a split adjusted basis. This compares with a net loss for the first nine months of 2016 of $9.5 million, or $2,232.30 per share based on 4,249 weighted average common shares outstanding on a split adjusted basis. The increase in net loss is due to an approximately $13.7 million increase in interest expense primarily related to the amortization of debt discounts and a $3.0 million loss related to two transactions to

settle convertible note debt, 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 $1.9 million increase in operating expenses and a $7.9 million change in the fair value of the warrant liability, a non-cash item, offset by a $0.5 million increase in gross profit.

Balance Sheet Highlights

As of September 30, 2017, Delcath had cash and cash equivalents of $2.5 million, compared with $4.4 million as of December 31, 2016. In addition, the Company had $8.3 million in restricted cash primarily related to the Convertible Notes issued in June 2016. During the nine months ended September 30, 2017, the Company used $11.7 million of cash to fund operating activities. Management believes that its capital resources are adequate to fund operating activities through January 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 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, 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 September 30,		Nine months ended September 30,	
	2017	**2016**	**2017**	**2016**
Product revenue	$ 684	$ 435	$ 2,011	$ 1,316
Cost of goods sold	172	112	527	373
Gross profit	512	323	1,484	943
Operating expenses:				
Selling, general and administrative expenses	2,860	2,361	7,807	7,025
Research and development costs	2,279	2,686	7,119	5,975
Total operating expenses	5,139	5,047	14,926	13,000
Operating loss	(4,627)	(4,724)	(13,442)	(12,057)
Change in fair value of the warrant liability, net	27	8,680	1,227	9,171
Gain on warrant extinguishment	-	-	9,613	-
Loss on debt settlement	(2,952)	-	(2,952)	-
Interest income (expense)	(5,042)	(4,963)	(20,324)	(6,584)
Other income (expense)	(2)	3	5	(15)
Net loss	$ (12,596)	$ (1,004)	$ (25,873)	$ (9,485)
Other comprehensive loss:				
Foreign currency translation adjustments	$ (15)	$ (2)	$ 7	$ (12)
Comprehensive Loss	$ (12,611)	$ (1,006)	$ (25,866)	$ (9,497)
Common share data:				
Basic and diluted loss per share*	$ (9.36)	$(230.99)	$ (34.99)	$(2,232.30)
Weighted average number of basic and diluted common shares outstanding*	1,401,413	4,349	754,421	4,249

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016 and a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017

DELCATH SYSTEMS, INC.
Consolidated Balance Sheets
as of September 30, 2017 and December 31, 2016
(in thousands, except share and per share data)

	September 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 2,495	$ 4,409
Restricted cash	8,362	27,287
Accounts receivables, net	298	403
Inventories	1,164	660
Prepaid expenses and other current assets	385	698
Deferred financing costs	529	699
Total current assets	13,233	34,156
Property, plant and equipment, net	1,253	1,083
Total assets	$ 14,486	$ 35,239
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$ 1,891	$ 594
Accrued expenses	3,755	3,407
Series C preferred shares	494	-
Convertible notes payable, net of debt discount	9,736	13,343
Warrant liability	16	18,751
Total current liabilities	15,892	36,095
Deferred revenue	-	30
Other non-current liabilities	444	604
Total liabilities	16,336	36,729
Commitments and contingencies (Note 12)		
Stockholders' deficit		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	-	-
Common stock, $.01 par value; 500,000,000 shares authorized; 1,426,153 and 11,805 shares issued and 1,425,862 and 11,750 shares outstanding at September 30, 2017 and December 31, 2016, respectively*	14	-
Additional paid-in capital	303,808	277,790
Accumulated deficit	(305,587)	(279,188)
Treasury stock, at cost; 1 share at September 30, 2017 and December 31, 2016, respectively*	(51)	(51)

Accumulated other comprehensive loss	(34)	(41)
Total stockholders' deficit	(1,850)	(1,490)
Total liabilities and stockholders' deficit	$ 14,486	$ 35,239

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016 and a one-for-three hundred and fifty (1:350) reverse stock split effected on November 6, 2017