Delcath Announces 2017 Financial Results

March 16, 2018

NEW YORK, March 16, 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 twelve months ended December 31, 2017.

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

- Revenue from European sales for 2017 increased 35% to $2.7 million from $2.0 million in 2016;
- Satisfaction of all obligations under the privately placed senior secured convertible notes issued to two institutional investors in June 2016;
- Completed a $5.0 million capital raise in February 2018;
- 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);
- Announced that the independent Data Safety Monitoring Board (DSMB) of the Phase 3 FOCUS clinical trial recommended that the study continue without modification; 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 through an agreement with Tillomed Laboratories for use with the company's CHEMOSAT® Delivery System for Melphalan, where it is marketed in Europe for the treatment of a wide range of cancers of the liver.

Management Commentary

"For much of the second half of 2017 and recent weeks, our focus has been on easing 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 necessitated a series of transactions during the second half of 2017 and the early weeks of 2018 that have permitted us to exit our 2016 Convertible Note, 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 to secure new equity financing under less dilutive terms to execute our plan and create value for our shareholders."

"Despite cash constraints, total revenues for fiscal year 2017 increased 35% over the prior year, 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, 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 OM liver metastases. We are hopeful that inclusion in the national guidelines and the support of clinicians treating patients with CHEMOSAT will support an application for reimbursement in this market. Since launching CHEMOSAT in Europe, over 500 commercial CHEMOSAT procedures have been performed.

"In our clinical development program, we achieved an important milestone in December 2017 when the independent DSMB for our Phase 3 FOCUS clinical trial for patients with hepatic dominant OM completed a pre-specified review of safety data and recommended that the study continue without modification. This confirms our own observations of the improvements in the safety profile of PHP therapy based on prior research and our commercial experience with CHEMOSAT in Europe. We were also happy to announce a SPA modification agreement with the FDA to revise the FOCUS trial's eligibility criteria to permit a greater extent of extra-hepatic disease by removing the size restriction, number and location of extra-hepatic lesions, in conjunction with a treatment plan for the extra-hepatic metastases. We requested this protocol modification to improve patient access to this important clinical trial for appropriately selected patients. In an ultra-orphan indication like OM, striking the appropriate balance between eligibility criteria and patient access can be a challenge. We are pleased that the FDA agreed to this modification, and hope that once approved by the European Competent Authorities, ethics boards and institutional review boards of our participating clinical trial sites, this protocol modification will help accelerate enrollment in this registration trial.

"Enrollment in our FOCUS Phase 3 Trial has been slower than anticipated, and our ability to take proactive steps to support enrollment was limited by the cash constraints we operated under in 2017. With the rollout of the SPA protocol modification to participating centers underway, we hope to accelerate enrollment in 2018 and expect to update our enrollment projections in the second half of this year. 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.

"For our pivotal trial in intrahepatic cholangiocarcinoma (ICC), we continue to work with potential trial sites with a view to opening the trial in the first half of 2018. 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. We have closed enrollment in the Phase 2 trials to devote available resources to the FOCUS Trial and the planned ICC pivotal trial.

"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.

2017 Financial Results

Total revenue for the year ended December 31, 2017 of $2.7 million was an increase of 35% when compared to the $2.0 million total for 2016. The increase is the result of greater product sales in Europe in 2017 as Delcath continued to see increased market acceptance of its product, particularly in Germany where the establishment of the ZE code contributed to an increase in treatments.

Research and development (R&D) expenses for 2017 increased to $10.5 million from $8.4 million for the prior year, largely as a result of costs associated with the Company's ongoing Phase 3 FOCUS Trial. Selling, general and administrative expenses for 2017 increased to $9.7 million from $9.4 million in 2016, primarily due to an increase in Delaware corporate taxes, independent audit fees, and costs associated with the Company's efforts to secure approval for a reverse stock split.

For the year ended December 31, 2017, derivative instrument income increased to $15.1 million from $12.8 million for the year ended December 31, 2016. The increase of $2.3 million is due to the issuance of the November 2017 warrants and the subsequent mark-to-market adjustment at December 31, 2017.

The Company had a net loss for the year ended December 31, 2017 of $45.1 million, an increase of $27.1 million, or 151.1%, compared to the net loss of $18.0 million for the same period in 2016. Approximately $2.3 million is related to an increase in operating expenses primarily related to increased investment in clinical trial initiatives. The balance of the increase is related to several non-cash items, including a $7.4 million increase in interest expense primarily related to the amortization of debt discounts and a $29.9 million loss on the settlement of the convertible note debt, which was partially offset by a $2.3 million change in the fair value of the warrant liability and a $9.6 million gain on the extinguishment of the June 2016 Series C Warrants.

The 2016 net loss included a $14.3 million increase in interest expense primarily related to the amortization of debt discounts and a $1.4 million increase in operating expenses primarily related to increased investment in clinical trial initiatives. This was offset by a $12.2 million change in the fair value of the warrant liability, a non-cash item, and a $0.2 million improvement in gross profit due to increased sales.

Balance Sheet Highlights

As of December 31, 2017, Delcath had cash and cash equivalents of $4.0 million, compared with $4.4 million as of December 31, 2016. During 2017 the Company used $15.4 million of cash to fund operating activities.

On February 9, 2018, the Company closed a registered offering of 212.0 million shares of common stock, 38.0 million pre-funded warrants to purchase 38.0 million shares of common stock and warrants to purchase an aggregate of 500.0 million shares of common stock for total gross proceeds of approximately $5.0 million.

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 plan to initiate a Registration 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: 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.
Consolidated Statements of Operations and Comprehensive Loss
for the twelve months ended December 31, 2017, 2016 and 2015
(in thousands, except share data)

	Year ended December 31,		
	2017	**2016**	**2015**
Revenue	$ 2,715	$ 1,992	$ 1,747
Cost of goods sold	(701)	(550)	(462)
Gross profit	2,014	1,442	1,285
Operating expenses:			
Selling, general and administrative expenses	9,684	9,434	10,009
Research and development expenses	10,495	8,448	6,486
Total operating expenses	20,179	17,882	16,495
Operating loss	(18,165)	(16,440)	(15,210)
Change in fair value of the warrant liability, net	15,103	12,780	564
Gain on warrant extinguishment	9,613	—	—
Loss on debt settlements and extinguishments	(29,924)	—	—
Interest expense	(21,703)	(14,328)	(67)
Other income (expense)	(41)	17	9
Net loss	$ (45,117)	$ (17,971)	$ (14,704)
Other comprehensive loss:			
Foreign currency translation adjustments	$ 83	$ (33)	$ (28)
Comprehensive loss	$ (45,034)	$ (18,004)	$ (14,732)
Common share data:			
Basic and diluted loss per share*	$ (6.50)	$ (3,707)	$ (5,096)
Weighted average number of basic and diluted shares outstanding*	7,019,316	4,847	2,887

*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 December 31, 2017 and 2016
(in thousands, except share and per share data)

	December 31, 2017	**December 31, 2016**
Assets		
Current assets		
Cash and cash equivalents	$ 3,999	$ 4,409
Restricted cash	1,325	27,287
Accounts receivables, net	317	403
Inventories	1,248	660
Prepaid expenses and other current assets	700	698
Deferred financing costs	—	699
Total current assets	7,589	34,156
Property, plant and equipment, net	1,298	1,083
Total assets	$ 8,887	$ 35,239
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 3,846	$ 594
Accrued expenses	3,408	3,407

Convertible notes payable, net of debt discount	—	13,343
Warrant liability	560	18,751
Total current liabilities	7,814	36,095
Deferred revenue	—	30
Other non-current liabilities	395	604
Total liabilities	8,209	36,729
Commitments and contingencies		
Stockholders' Equity (Deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	—	—
Common stock, $.01 par value; 500,000,000 shares authorized; 114,055,137 and 11,805 shares issued and 114,054,851 and 11,750 shares outstanding at December 31, 2017 and December 31, 2016, respectively*	1,141	—
Additional paid-in capital	324,378	277,790
Accumulated deficit	(324,832)	(279,188)
Treasury stock, at cost; 1 share at December 31, 2017 and December 31, 2016, respectively*	(51)	(51)
Accumulated other comprehensive loss	42	(41)
Total stockholders' equity (deficit)	678	(1,490)
Total liabilities and stockholders' equity (deficit)	$ 8,887	$ 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.