Delcath Announces 2016 Financial Results

NEW YORK, March 29, 2017 — Delcath Systems, Inc. (NASDAQ:DCTH), an interventional oncology Company focused on the treatment of primary and metastatic liver cancers, announces financial results for the 12 months ended December 31, 2016.

Highlights for the fourth quarter of 2016 and recent weeks include:

- Fourth quarter 2016 revenue increased 54.0% to $0.7 million and full year 2016 revenue increased 18% to $2.0 million;
- Fully established national reimbursement coverage in Germany under ZE system;
- Significantly expanded the number of clinical sites for the Company's global Phase 3 clinical trial for patients with hepatic dominant ocular melanoma (the FOCUS Trial);
- Announced a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for the design of a pivotal trial of Melphalan/HDS to treat patients with intrahepatic cholangiocarcinoma (ICC);
- The *American Journal of Clinical Oncology* published a single-center retrospective review finding that the Company's investigational percutaneous hepatic perfusion (PHP) with Melphalan/HDS offered promising results with a doubling of overall survival and significantly longer progression-free survival (PFS) and hepatic progression-free survival (HPFS) compared with other targeted therapies; and
- Favorable data from two institutions were presented at the Regional Cancer Therapies Symposium and showed strong tumor response and overall survival with the Company's investigational PHP therapy in patients with ocular melanoma that metastasized to the liver.

"Fiscal year 2016 was devoted to the advancement of our global FOCUS Trial in ocular melanoma liver metastases as well as other important clinical initiatives for our Melphalan/HDS as a treatment for primary and metastatic liver cancers, while at the same time we continued to facilitate the commercial availability of CHEMOSAT in Europe," said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Office of Delcath.

"Our FOCUS Trial was initiated in January 2016 under an SPA with the FDA to evaluate Melphalan/HDS as a treatment for ocular melanoma that has metastasized to the liver. During the year we activated more than 20 leading U.S. and European cancer centers as participating clinical sites in this study. We plan to have approximately 40 sites activated by the end of summer 2017.

"In addition, we recently announced a new SPA with the FDA for the initiation of a pivotal trial for the use of Melphalan/HDS in patients with ICC. This new trial will enroll approximately 295 ICC patients at approximately 40 clinical sites in the U.S. and Europe, with the primary endpoint of overall survival and secondary and exploratory endpoints including safety,

progression-free survival, overall response rate and quality-of-life measures. We've designed this trial to be cost effective and intend to pursue it in a financially prudent manner. Given the sequential nature of the trial design, our investment in this study will be modest in 2017 as the Melphalan/HDS segment of the study will not occur until late in the year.

"In Europe, we continued to grow revenue and focus our efforts on obtaining favorable reimbursement in key markets. We believe our ZE national reimbursement in Germany, along with the continued presentation and publication of data supporting the use of CHEMOSAT by leading clinical experts validates our access efforts in other markets across Europe.

"During the year we also secured committed financing through a securities purchase agreement with an institutional investor to issue $35 million of senior convertible notes and common stock purchase warrants. Assuming all conditions are satisfied, we expect the quarterly releases of capital throughout 2017 will fund our clinical development plan through the end of the year, while also supporting our commercial activities in Europe.

"The commercial and clinical progress made throughout 2016 has been steady and we look forward to expanding access to our potentially life-saving PHP therapy for patients around the world afflicted with primary and metastatic liver cancer," concluded Dr. Simpson.

2016 Financial Results

Total revenue for 2016 of $2.0 million increased 18% from $1.7 million for 2015. Selling, general and administrative expenses for 2016 decreased to $9.4 million from $10.0 million in 2015. For 2016, research and development expenses increased to $8.4 million from $6.5 million in 2015. Total operating expenses for 2016 were $17.9 million compared with $16.5 million for 2015.

The Company reported a net loss for 2016 of $18.0 million or $10.59 per share based on 1.7 million weighted average common shares outstanding, compared with a net loss for 2015 of $14.7 million or $14.56 per share based on 1.0 million weighted average common shares outstanding. The increase is primarily due to a $14.3 million increase in interest expense primarily related to the amortization of debt discounts, a non-cash item, 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 higher sales.

Balance Sheet Highlights

As of December 31, 2016, Delcath had cash and cash equivalents of $4.4 million, compared with $12.6 million as of December 31, 2015. During 2016 the Company used $14.2 million of cash to fund operating activities. Delcath believes it has sufficient capital and access to committed capital to fund its operating activities through the first quarter 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) 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, our ability to maintain NASDAQ listing, 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.

-Tables to Follow-

Delcath Systems, Inc.
Consolidated Statements of Operations and Comprehensive Loss
for the twelve months ended December 31, 2016 and 2015
(in thousands, except share data)

	Year ended December 31,	
	2016	**2015**
Product revenue	$ 1,992	$ 1,747
Cost of goods sold	(550)	(462)
Gross profit	1,442	1,285
Operating expenses:		
Selling, general and administrative expenses	9,434	10,009
Research and development costs	8,448	6,486
Total operating expenses	17,882	16,495
Operating loss	(16,440)	(15,210)
Derivative instrument income	12,780	564
Interest income	17	9
Other expense and interest expense	(14,328)	(67)
Net loss	$ (17,971)	$ (14,704)
Other comprehensive loss:		
Foreign currency translation adjustments	$ (33)	$ (28)
Comprehensive Loss	$ (18,004)	$ (14,732)
Common share data:		
Basic and diluted loss per share*	$ (10.59)	$ (14.56)
Weighted average number of basic and diluted shares outstanding*	1,696,237	1,010,105

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

DELCATH SYSTEMS, INC.
Consolidated Balance Sheets
as of December 31, 2016 and December 31, 2015
(in thousands, except share and per share data)

	December 31, 2016	**December 31, 2015**
Assets		
Current assets		

Cash and cash equivalents	$ 4,409	$ 12,607
Restricted cash	27,287	–
Accounts receivables, net	403	277
Inventories	660	757
Prepaid expenses and other current assets	698	960
Deferred financing costs	699	–
Total current assets	34,156	14,601
Property, plant and equipment, net	1,083	1,132
Total assets	$ 35,239	$ 15,733
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 594	$ 284
Accrued expenses	3,407	2,243
Convertible notes payable, net of debt discount	13,343	–
Warrant liability	18,751	3,785
Total current liabilities	36,095	6,312
Deferred revenue	30	–
Other non-current liabilities	604	820
Total liabilities	36,729	7,132
Commitments and contingencies (Note 12)		
Stockholders' Equity (Deficit)		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	–	–
Common stock, $.01 par value; 500,000,000 shares authorized; 4,131,527 and 1,396,348 shares issued and 4,112,417 and 1,360,239 shares outstanding at December 31, 2016 and December 31, 2015, respectively*	41	14
Additional paid-in capital	277,749	269,863
Accumulated deficit	(279,188)	(261,217)
Treasury stock, at cost; 110 shares at December 31, 2016 and December 31, 2015, respectively*	(51)	(51)
Accumulated other comprehensive loss	(41)	(8)
Total stockholders' equity (deficit)	(1,490)	8,601
Total liabilities and stockholders' equity (deficit)	$ 35,239	$ 15,733

*reflects a one-for-sixteen (1:16) reverse stock split effected on July 21, 2016

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