Delcath Announces First Quarter Financial Results

NEW YORK, May 4, 2016 — Delcath Systems, Inc. (NASDAQ: DCTH), a specialty pharmaceutical and medical device company focused on oncology with an emphasis on the treatment of primary and metastatic liver cancers, announces financial results for the three months ended March 31, 2016.

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

- Initiation of patient enrollment in the global Phase 3 *FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma* (the FOCUS trial), which is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) to support marketing approval in the U.S.
- Addition of two prestigious U.S. cancer centers as FOCUS trial clinical sites
- Activation of Hacettepe University Clinic in Ankara, Turkey as the first CHEMOSAT commercial treatment center outside of the European Union
- Initiation of hospital negotiations for definition of ZE reimbursement levels in Germany
- Completion of more than 300 treatments with CHEMOSAT since the second generation of the system was launched

“We began 2016 with strong momentum in our clinical development program, kicking off the year with the acceptance of a SPA agreement with the FDA for initiation of our FOCUS Phase 3 trial,” said Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Office of Delcath. “We are delighted that three leading U.S. cancer centers are now open and several others have committed to participate in the FOCUS trial and we look forward to opening additional trial sites in both the U.S. and Europe over the course of 2016. We made further progress with our Phase 2 trial for hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC) and expect to report interim data on the ICC cohort mid-year.

“We also continued to make steady progress commercializing CHEMOSAT in Europe. In February hospitals in Germany began negotiations to determine coverage levels for CHEMOSAT under the ZE national reimbursement mechanism. We anticipate coverage levels to be defined in mid-to-late 2016, which we believe will enhance growth in procedure volumes in Germany beginning late this year and provide important validation for reimbursement appeals in other markets in Europe.

“In April we announced our first expansion into markets outside of the European Union with the activation of Hacettepe University Clinic in Ankara, Turkey. Hacettepe is a well-regarded cancer treatment center in Turkey, and we believe it will serve as an excellent hub for CHEMOSAT treatments in the entire region.

“We look forward to executing our strategic plan throughout the remainder of the year, which

includes multiple presentations and publications of data in support of CHEMOSAT as a treatment for metastatic liver cancers," concluded Dr. Simpson.

First Quarter Financial Results

Total revenue for the first quarter of 2016 was $0.4 million. Selling, general and administrative expenses for the first quarter of 2016 were $2.4 million, an improvement of $0.6 million or 20% from $3.0 million reported for the same period in 2016, primarily attributable to a reduction in severance accruals related to workforce and lease restructurings. Research and development expenses increased to $1.3 million for the 2016 first quarter from $1.0 million for the same period in 2015, primarily due to increased investment in clinical development initiatives.

Total operating expenses for the first quarter of 2016 decreased to $3.7 million from $4.0 million for the same period in 2015. This reflects an increase in clinical development initiatives, partially offset by a reduction in severance and compensation-related expenses following significant workforce and lease restructurings, as well as a reduction in facility expenses.

The Company recorded a net loss for the three months ended March 31, 2016 of $1.8 million, a decrease of $1.7 million or 49% from a net loss of $3.5 million for the same period in 2015. This decrease in net loss is primarily due to a $1.3 million change in the fair value of the warrant liability, a non-cash item and a $0.3 million reduction in operating expenses.

Balance Sheet Highlights

As of March 31, 2016, Delcath had cash and cash equivalents of $9.5 million, compared with $12.6 million as of December 31, 2015. During the first quarter of 2016, the Company used $3.8 million in cash to fund its operating activities. Delcath believes it has sufficient capital to fund its operating activities through the third quarter of 2016.

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology with a principal focus on the treatment of primary and metastatic liver cancers. Our proprietary 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. In April 2012 we obtained authorization to affix a CE Mark to our second-generation system, which is currently marketed in Europe as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In the U.S. the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the U.S. Food and Drug Administration (FDA). Melphalan/HDS has not been approved for sale in the U.S. We have commenced our global Phase 3 FOCUS clinical

trial for Patients with Hepatic Dominant Ocular Melanoma (OM) and a global Phase 2 clinical trial in Europe and the U.S. to investigate the Melphalan/HDS system for the treatment of primary liver cancer (HCC) and intrahepatic cholangiocarcinoma (ICC).

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, HCC ,and ICC clinical trial programs, timely enrollment and treatment of patients in the global Phase 3 FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma and the global Phase 2 HCC and ICC clinical trials, IRB or ethics committee clearance of the Phase 2 HCC/ICC and/or Phase 3 OM protocols from participating sites and the timing of site activation and subject enrollment in each trial, the impact, if any, of publication of the Phase 3 trial manuscript to support the Company's efforts, 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, the Company's ability to successfully commercialize the CHEMOSAT/Melphalan HDS system and the potential of the CHEMOSAT/Melphalan HDS 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, the Company's ability to satisfy the remaining requirements of the FDA's Complete Response Letter and provide the same in a timely manner, 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.

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

	March 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 9,545	$ 12,607
Accounts receivables, net	197	277
Inventories	835	757
Prepaid expenses and other current assets	880	960
Total current assets	11,457	14,601
Property, plant and equipment, net	1,070	1,132
Total assets	$ 12,527	$ 15,733
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 128	$ 284
Accrued expenses	1,723	2,243
Warrant liability	2,051	3,785
Total current liabilities	3,902	6,312
Other non-current liabilities	767	820
Total liabilities	4,669	7,132
Commitments and contingencies	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	–	–
Common stock, $.01 par value; 170,000,000 shares authorized; 24,696,248 and 22,341,574 shares issued and 24,118,491 and 21,763,817 shares outstanding at March 31, 2016 and December 31, 2015, respectively	247	223
Additional paid-in capital	270,692	269,654
Accumulated deficit	(263,030)	(261,217)
Treasury stock, at cost; 1,757 shares at March 31, 2016 and December 31, 2015, respectively	(51)	(51)
Accumulated other comprehensive income	–	(8)
Total stockholders' equity	7,858	8,601
Total liabilities and stockholders' equity	$ 12,527	$ 15,733

Delcath Systems, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss

for the three months ended March 31, 2016 and 2015

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2016	**2015**
Revenue	$ 370	$ 444
Cost of goods sold	(111)	(133)
Gross profit	259	311
Operating expenses:		
Selling, general and administrative	2,377	3,040
Research and development	1,344	979
Total operating expenses	3,721	4,019
Operating loss	(3,462)	(3,708)
Change in fair value of the warrant liability, net	1,672	209
Other income (expense)	(23)	11
Net loss	$ (1,813)	$ (3,488)
Other comprehensive income (loss):		
Foreign currency translation adjustments	8	(14)
Comprehensive loss	$ (1,805)	$ (3,502)
Common share data:		
Basic and diluted loss per common share	$ (0.08)	$ (0.32)
Weighted average number of basic and diluted common shares outstanding	23,288,697	10,857,142

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/delcath-announces-first-quarter-financial-results-300262116.html

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