Delcath Announces 2015 Fourth Quarter and Full Year Financial Results

Quarterly and yearly revenue grow more than 50% compared with 2014

NEW YORK, March 21, 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 and 12 months ended December 31, 2015.

Highlights for the fourth quarter of 2015 and recent weeks include:

- Fourth quarter 2015 revenue increased 51% to $0.4 million and full year 2015 revenue of $1.7 million increased 63% compared with 2014;
- Initiation of patient enrollment in the global Phase III trial: *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.;
- Publication of prior Phase 3 metastatic melanoma clinical trial results in the prestigious peer-reviewed journal *Annals of Surgical Oncology;*
- Establishment in Germany of the first national reimbursement mechanism for the Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT);
- Initiation of patient enrollment and first patients treated in the intrahepatic cholangiocarcinoma (ICC) cohort of the Company's European Phase 2 HCC/ICC program; and
- Completion of more than 300 treatments with CHEMOSAT since the second generation of the system was launched.

"Throughout 2015 we advanced every key element of our clinical development program and commercialization priorities for CHEMOSAT, achieving noteworthy milestones in all areas of our strategic plan," said Dr. Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Office of Delcath. "Our efforts in 2015 allowed us to kick off 2016 with the agreement by the FDA of our request for a Special Protocol Assessment of a clinical protocol for initiation of the FOCUS trial in January of this year. If successful, the FOCUS trial will provide a clear pathway to approval for the treatment of hepatic dominant ocular melanoma for Melphalan/HDS. We are delighted to have a number of leading U.S. cancer centers committed to participate in this study and look forward to opening these sites in the coming months. Proceeding with the trial under the SPA agreement also represents the satisfaction of a substantial number of the requirements of the FDA's 2013 Complete Response Letter. During 2015 we also advanced our Phase 2 clinical trial program in Europe for intrahepatic cholangiocarcinoma, with the ICC cohort now open for enrollment and treating patients.

"We are particularly pleased with the steady progress we are making with the commercialization of CHEMOSAT in Europe. Product revenue for the year was $1.7 million, an

increase of more than 60% compared with 2014. Importantly, we received our first national reimbursement coverage with the establishment of ZE reimbursement for CHEMOSAT procedures in Germany. We anticipate coverage levels for CHEMOSAT to be defined by mid-2016, and together with publication of our prior Phase 3 clinical trial results, expect they will provide important support for the growth of CHEMOSAT procedures in Germany and will enhance our reimbursement efforts in other European markets. During the year, we were particularly pleased to report the completion of more than 300 CHEMOSAT procedures since adopting the second generation of the filtration system. In addition to the steady growth in commercial procedures, clinical data obtained with CHEMOSAT were presented at five international medical conferences and published in two peer-reviewed journals.

“Our team continues to execute effectively on our strategic plan while maintaining disciplined expense management, and is entirely focused on delivering value for shareholders. We look forward to continuing this momentum in 2016 and beyond,” concluded Dr. Simpson.

Fourth Quarter Financial Results

Total revenue for the fourth quarter of 2015 was $0.4 million, a 51% increase from the $0.3 million reported for the fourth quarter of 2014. Selling, general and administrative expenses during the fourth quarter of 2015 were $2.2 million, a decrease of $0.6 million or 23% from the $2.8 million reported for the same period in 2014. Research and development expenses increased to $2.4 million in the 2015 fourth quarter from $0.7 million for the same period in 2014, primarily due to increased clinical development initiatives. The increase was partially offset by organizational efficiencies implemented through a phase out of the medical science liaison program and workforce restructurings.

Total operating expenses for the fourth quarter of 2015 increased by 31% to $4.6 million from the $3.5 million reported for the same period in 2014. This reflects an increase in our clinical development initiatives, which was partially offset by a reduction in severance and compensation-related expenses following significant workforce and lease restructurings throughout 2014 and 2015, as well as a reduction in facility expenses.

The Company recorded a net loss for the 2015 fourth quarter of $5.1 million, or $0.23 per share, an increase of $2.1 million or 73%, compared with a net loss of $2.9 million, or $0.31 per share, for the same period in 2014. This increase is primarily due to a $1.1 million increase in operating expenses, a $0.1 million improvement in gross profit and a $1.2 million change in the fair value of the warrant liability, a non-cash item.

2015 Financial Results

Total revenue for 2015 of $1.7 million increased 63% from the $1.1 million reported for 2014. Selling, general and administrative expenses for 2015 were $10.0 million, a decrease of $5.8 million or 37% from $15.8 million in 2014. For 2015, research and development expenses

increased to $6.5 million from the $4.3 million reported in 2014.

Total operating expenses for 2015 decreased by 18% to $16.5 million from $20.1 million for 2014.

The Company reported a net loss in 2015 of $14.7 million, a decrease of $2.7 million, or 15%, compared with the net loss for 2014. This decrease is primarily due to a $3.6 million decrease in operating expenses and a $0.5 million improvement in gross profit, which was offset by a $1.4 million change in the fair value of the warrant liability, a non-cash item.

Balance Sheet Highlights

As of December 31, 2015, Delcath had cash and cash equivalents of $12.6 million, compared with $20.5 million as of December 31, 2014. During 2015, the Company used $16.4 million of cash for 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 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, 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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-Tables to Follow-

DELCATH SYSTEMS, INC.
Consolidated Balance Sheets
as of December 31, 2015 and December 31, 2014
(in thousands, except share data)

	December 31, 2015	December 31, 2014
Assets:		
Current assets		
Cash and cash equivalents	$ 12,607	$ 20,469
Accounts receivables, net	277	174
Inventories	757	349

Prepaid expenses and other current assets	960	974
Total current assets	14,601	21,966
Property, plant and equipment, net	1,132	1,798
Total assets	$ 15,733	$ 23,764
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$ 284	$ 748
Accrued expenses	2,243	3,603
Warrant liability	3,785	225
Total current liabilities	6,312	4,576
Other non-current liabilities	820	1,043
Total liabilities	7,132	5,619
Commitments and contingencies	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	–	–
Common stock, $.01 par value; 170,000,000 shares authorized; 22,341,574 and 9,740,394 shares issued and 21,763,817 and 9,708,841 shares outstanding at December 31, 2015 and December 31, 2014, respectively	223	97
Additional paid-in capital	269,654	264,592
Accumulated deficit	(261,217)	(246,513)
Treasury stock, at cost; 1,757 shares at December 31, 2015 and December 31, 2014, respectively	(51)	(51)
Accumulated other comprehensive income	(8)	20
Total stockholders' equity	8,601	18,145
Total liabilities and stockholders' equity	$ 15,733	$ 23,764

Delcath Systems, Inc.
Consolidated Statements of Operations and Comprehensive Loss
for the three and twelve months ended December 31, 2015 and 2014
(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2015	**2014**	**2015**	**2014**
Revenue	$ 439	$ 291	$ 1,747	$ 1,069
Other revenues	–	–	–	–
Total revenue	439	291	1,747	1,069
Cost of goods sold	(102)	(81)	(462)	(291)
Gross profit	337	210	1,285	778
Operating expenses:				
Selling, general and administrative	2,191	2,828	10,009	15,783
Research and development	2,374	667	6,486	4,299

Total operating expenses	4,565	3,495	16,495	20,082
Operating loss	(4,228)	(3,285)	(15,210)	(19,304)
Derivative instrument income	(850)	330	564	1,942
Interest income	3	1	9	5
Other expense and interest expense	(18)	9	(67)	(24)
Net loss	$ (5,093)	$ (2,945)	$ (14,704)	$ (17,381)
Common share data:				
Basic and diluted loss per common share	$ (0.23)	$ (0.31)	$ (0.91)	$ (1.84)
Weighted average number of basic and diluted common shares outstanding	21,763,876	9,632,192	16,161,687	9,452,050
Other comprehensive income (loss):				
Foreign currency translation adjustments	$ (23)	$ (70)	$ (28)	$ (76)
Comprehensive loss	$ (5,116)	$ (3,015)	$ (14,732)	$ (17,457)

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