



## **DELCATH REPORTS FOURTH QUARTER AND FULL YEAR 2012 RESULTS**

*– Conference Call and Webcast Today at 4:30 p.m. ET –*

**NEW YORK, March 13, 2013** – Delcath Systems, Inc. (NASDAQ: DCTH) today reported financial results and operational highlights for the fiscal fourth quarter and full year ended December 31, 2012.

Highlights from the 2012 fiscal year and recent weeks include:

- Acceptance by the U.S. Food and Drug Administration (FDA) for substantive review of the Company's New Drug Application (NDA) for its proprietary drug/device combination product with the proposed brand name of Melblez Kit™ (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), with a proposed indication for the treatment of patients with unresectable ocular melanoma metastatic to the liver – the FDA assigned a PDUFA goal date of June 15, 2013
- Announcement of an Oncologic Drugs Advisory Committee (ODAC) panel meeting on May 2, 2013 to assess the Company's NDA
- Initiation of U.S. Expanded Access Program (EAP) and treatment of first EAP patient in the U.S.
- Q4 cash utilization reduced by 33% compared to Q3
- First commercial sales in Company history
- Treatment of first patients in Europe with the CHEMOSAT® Hepatic Delivery System for melphalan hydrochloride
- Value 4 interim reimbursement coverage granted in Germany and identified an existing DRG code for partial reimbursement in Italy—hospitals submitting interim reimbursement applications in both countries
- Receipt of CE Mark approval for CHEMOSAT Hepatic Delivery System to deliver and filter doxorubicin hydrochloride injection

“Last year was one of significant accomplishments for Delcath, led by the FDA’s acceptance of our NDA for the Melblez Kit System for substantive review,” said Eamonn P. Hobbs, President and CEO of Delcath Systems. “Submission of our application was the culmination of an intensive effort by our team, and FDA’s acceptance of our NDA and designation of a June 15, 2013 PDUFA goal date are the most important developments in our history. During the year, we also established our initial commercial footprint in Europe, recorded our first commercial sales, and in recent weeks began negotiations with the FDA on our Clinical Development Program with the goal of expanding the label for concentrated, liver-directed therapy.”

“We introduced CHEMOSAT into Europe this past year, establishing a presence for the treatment in all seven of our target countries,” continued Mr. Hobbs. “Patients with liver dominant disease from multiple tumor types have been treated, and physician interest in the therapeutic approach with CHEMOSAT remains strong. We believe publication of our Phase 3

melanoma and Phase 2 multi-histology clinical trial data will further drive this interest. Development of compelling reimbursement is a key driver of utilization and revenue growth. We are working closely with experts and our partner hospitals to bring various interim reimbursement mechanisms online, and in parallel are engaged in the applications process to establish permanent, compelling reimbursement. Though these mechanisms have come online slower than we anticipated, which has impacted revenue ramp, physician interest in our therapy is strong and we remain optimistic about the long-term prospects for CHEMOSAT in Europe.”

“In the United States, we continue to work closely with the FDA in its evaluation of our NDA, and are preparing for our presentation to the ODAC panel on May 2<sup>nd</sup>. Our engagement with the FDA has been constructive, and we are hopeful that the agency will conclude its review on the PDUFA goal date. Assuming our NDA is approved, our plan is to launch in the U.S. during the fourth quarter, focusing initially on those hospitals that are participating in our recently launched EAP and have participated in our clinical trials. With that goal in mind, we are currently evaluating an ultra-orphan pricing and commercialization strategy in the U.S. for unresectable metastatic ocular melanoma,” concluded Mr. Hobbs.

#### **Fourth Quarter and Full Year Financial Results**

For the three months ended December 31, 2012, Delcath recorded revenue of \$0.2 million. Operating loss was \$11.8 million, which included approximately \$0.9 million in non-cash stock-based compensation expense, as compared with an operating loss of \$16.0 million, including \$0.9 million in non-cash stock-based compensation expense, in the same prior year period. Selling, general and administrative (SG&A) expenses were \$6.4 million for the fourth quarter of 2012, compared to \$6.1 million for the same period in 2011. The higher SG&A expense was primarily due to increased EU commercialization expenses. Research and development (R&D) expenses were \$5.6 million for the fourth quarter of 2012, compared to \$9.8 million for the same period in 2011. The lower R&D expenses reflect lower consulting expenses following the submission of the NDA on August 15, 2012.

For the year ended December 31, 2012, Delcath recorded revenue of \$0.3 million and an additional \$30,000 of deferred revenue related to orders from distribution partners. The Company's operating loss was \$53.9 million, which included approximately \$3.8 million in non-cash stock-based compensation expense. The increase in expense is primarily related to EU commercialization efforts. Operating loss for the year ended December 31, 2011 was \$46.5 million, which included approximately \$4.3 million in non-cash stock-based compensation expense. SG&A expenses were \$28.0 million for the year ended December 31, 2012, compared to \$21.3 million for the year ended December 31, 2011. R&D expenses were \$26.2 million for the year ended December 31, 2012, compared to \$25.2 million during the year ended December 31, 2011.

At December 31, 2012, cash, cash equivalents and certificates of deposit were \$23.7 million, compared with \$30.8 million at December 31, 2011. For the fourth quarter cash utilization was \$9.7 million, a 33% reduction compared to \$14.6 million in the third quarter. This was consistent with the Company's previously announced expectations for average monthly cash utilization between \$3 million and \$4 million for the fourth quarter. The decrease in cash utilization was

primarily driven by a reduction in consulting services following submission of the NDA as well as overall effective cost management.

The Company successfully completed its “at the market” (ATM) equity offering program, and between January 1, 2013 and February 28, 2013 raised approximately \$20.9 million before related expenses. At February 28, 2013, the Company’s cash and cash equivalents were approximately \$38 million (unaudited). The Company has entered into a new ATM equity offering program, under which the Company may sell up to \$50 million in its common stock from time to time once the associated shelf registration statement becomes effective.

“We remain committed to maintaining our reduced quarterly cash utilization of \$9 million to \$12 million for 2013,” said Graham Miao, Ph.D., Delcath’s Chief Financial Officer. “We believe that with our current cash balance and access to capital resources, we have the financial resources and flexibility to execute our operating plan for the next twelve months and beyond.”

### **Conference Call and Webcast**

The Company will host a conference call today, March 13, 2013 at 4:30 p.m. ET. The dial-in numbers for the conference call are 877-299-4454 (U.S. participants) and 617-597-5447 (International participants); both numbers require passcode 99502530. To access the live webcast, go to the Events & Presentations page on the Investor Relations section of the Company's website at <http://www.delcath.com/investors/events/>.

A taped replay of the call will be available beginning approximately two hours after the call's conclusion and will be available for seven days. Dial-in numbers for the replay are 888-286-8010 and 617-801-6888 for U.S. and International callers, respectively. The replay passcode for both U.S. and international callers is 41198605. An archived webcast will also be available at <http://www.delcath.com/investors/events/>.

### **About Delcath Systems**

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product, the Delcath Hepatic Delivery System, is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers. In 2010, Delcath announced that its randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company also completed a multi-arm Phase 2 trial to treat other liver cancers. Outside of the United States, our proprietary product to deliver and filter melphalan hydrochloride is marketed under the trade name Delcath Hepatic CHEMOSAT<sup>®</sup> Delivery System (CHEMOSAT Delivery System for Melphalan.) The Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan in April 2012. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT Delivery System for Melphalan in Europe. In October 2012, the Company satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery

System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin hydrochloride injection (CHEMOSAT Delivery System for Doxorubicin), providing a regulatory pathway for the CHEMOSAT Delivery System for Doxorubicin for countries in Asia that accept the CE Marking as part of their national regulatory requirements. The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company's NDA has been accepted for filing and substantive review by the FDA. For more information, please visit the Company's website at [www.delcath.com](http://www.delcath.com).

*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 outcome of the ODAC meeting, and the impact, if any, of the advisory panel's recommendation on the FDA's decision regarding the Company's new drug application (NDA), timing of completion of the FDA's review of our NDA, the extent to which the FDA may request additional information or data and our ability to provide the same in a timely manner, acceptability of the Phase 1, 2 and 3 clinical trial data by the FDA, FDA approval of the Company's NDA for the treatment of ocular metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with primary and metastatic disease in the liver, market acceptance of the Gen Two CHEMOSAT system and patient outcomes using the same, approval of the current or future chemosaturation system for delivery and filtration of melphalan, doxorubicin or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets including Australia and key Asian markets and timing an revenue, if any, of the same, the approval of the Hepatic CHEMOSAT Delivery System device to deliver and filter doxorubicin in key Asian markets and patient outcomes using the same, our ability to obtain reimbursement for the CHEMOSAT system, uncertainties relating to the timing and results of research and development projects, uncertainties relating to the timing and results of future clinical trials, and uncertainties regarding our ability to obtain financial and other resources for any research, development 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.*

**Contact Information:**

Investors:	Financial Media
Gregory Gin/Patty Eisenhour	Chris Gale
EVC Group	EVC Group
646-445-4801/951-316-0577	646-201-5431

**DELCATH SYSTEMS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**for the Three Months and Years ended December 31, 2012 and 2011**  
**(in thousands, except share and per share data)**

	<b>Three months ended December 31,</b>		<b>Year ended December 31,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Revenue	\$ 200	\$ -	\$ 346	\$ -
Cost of goods sold	(39)	-	(39)	-
Gross profit	161	-	307	-
Operating expenses:				
Selling, general and administrative <sup>1</sup>	\$ 6,360	\$ 6,134	\$ 27,963	\$ 21,283
Research and development <sup>1</sup>	5,626	9,840	26,215	25,173
Total operating expenses	11,986	15,974	54,178	46,456
Operating loss	(11,825)	(15,974)	(53,871)	(46,456)
Change in fair value of warrant liability, net	1,134	702	2,159	15,566
Interest income	4	4	19	5
Other expense and interest expense	30	-	(175)	-
Net loss	\$ (10,657)	\$ (15,268)	\$ (51,868)	\$ (30,885)
Common share data:				
Basic and diluted loss per share	\$ (0.14)	\$ (0.32)	\$ (0.85)	\$ (0.68)
Weighted average number of basic and diluted common shares outstanding	74,440,509	48,000,168	61,275,527	45,236,921
Other comprehensive income (loss):				
Foreign currency translation adjustments	\$ (46)	\$ -	\$ 37	\$ -
Unrealized loss on securities	-	40	-	26
Other comprehensive income (loss), total	(46)	40	37	26
Comprehensive loss	\$ (10,703)	\$ (15,228)	\$ (51,831)	\$ (30,859)

Note 1:

Includes non-cash stock-based compensation as follows:

	<b>Three months ended December 31,</b>		<b>Year ended December 31,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
General and administrative expenses	\$ 569	\$ 558	\$ 2,398	\$ 2,744
Research and development costs	334	343	1,427	1,515
Total stock-based compensation expense	\$ 903	\$ 901	\$ 3,825	\$ 4,259

**DELCATH SYSTEMS, INC.**  
**Consolidated Balance Sheets**  
**as of December 31, 2012 and December 31, 2011**  
(in thousands, except share data)

	<b>December 31, 2012</b>	<b>December 31, 2011</b>
<b>Assets:</b>		
Current assets		
Cash and cash equivalents	\$ 23,726	\$ 25,777
Investments – Certificates of deposit	-	4,980
Accounts receivables	144	-
Inventories	1,105	-
Prepaid expenses and other current assets	1,457	1,231
Total current assets	26,432	31,988
Property, plant and equipment, net	4,042	3,253
Total assets	\$ 30,474	\$ 35,241
<b>Liabilities and Stockholders' Equity:</b>		
Current liabilities		
Accounts payable	\$ 939	\$ 925
Accrued expenses	5,790	5,473
Warrant liability	3,427	2,439
Total current liabilities	10,156	8,837
Deferred revenue	309	300
Commitments and contingencies	-	-
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2012 and December 31, 2011	-	-
Common stock, \$.01 par value; 170,000,000 shares authorized; 76,849,033 and 48,237,630 shares issued and 76,820,933 and 48,209,530 shares outstanding at December 31, 2012 and December 31, 2011, respectively	768	482
Additional paid-in capital	218,063	172,613
Accumulated deficit	(198,808)	(146,940)
Treasury stock, at cost; 28,100 shares at December 31, 2012 and December 31, 2011	(51)	(51)
Accumulated other comprehensive income	37	-
Total stockholders' equity	20,009	26,104
Total liabilities and stockholders' equity	\$ 30,474	\$ 35,241