# Delcath Announces Second Quarter Financial Results

August 16, 2016

NEW YORK, Aug. 16, 2016 /PRNewswire/ -- 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 six months ended June 30, 2016.

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

- Issuance of $35 million in senior convertible notes to support Melphalan/HDS Phase 3 Focus Trial enrollment and CHEMOSAT European commercialization through the end of 2017;
- Presentation of data from a large single hospital experience conducted at Southampton University Hospital in the United Kingdom at the 6th European Post-Chicago Melanoma/Skin Cancer Meeting, which demonstrated overall survival benefit using Delcath's CHEMOSAT to treat metastatic uveal melanoma;
- Acceptance of abstracts from two studies conducted in Germany using Delcath's CHEMOSAT® to treat patients with liver metastases for presentation as posters at the Cardiovascular and Interventional Radiology Society of Europe (CIRSE) Annual Meeting in September 2016;
- Acceptance of a review of clinical research treatment outcomes using Melphalan Hydrochloride for Injection with the Delcath Hepatic Delivery System (Melphalan/HDS) in patients with hepatic metastases for publication in the prestigious journal, *Cancer Control*;
- Promotion of John Purpura to Executive Vice President, Global Head of Operations from Executive Vice President-Regulatory Affairs and Quality Assurance; and
- Launch of CHEMOSAT at the HM Sanchinarro University Hospital in Madrid.

"Throughout the second quarter we made considerable clinical and commercial progress advancing CHEMOSAT as an innovative new treatment option for primary and metastatic liver cancers," noted Jennifer K. Simpson, Ph.D., MSN, CRNP, President and Chief Executive Officer of Delcath. "Importantly, we secured $35 million in committed financing that provides us with the resources to advance our clinical development plan through to key inflection points while also supporting our commercialization programs in Europe.

"We were particularly pleased to have real-world data from Southampton University Hospital's experience presented at the Melanoma/Skin Cancer meeting as the progression free and overall survival benefits observed in this study are dramatic, especially given the limited treatment options for patients suffering with these life-threatening cancers. These supportive data provide us with considerable confidence that similar results may be formally validated by our FOCUS Phase 3 Trial in hepatic dominant ocular melanoma that is currently underway in the U.S. and Europe. We look forward to additional presentations and publication of data in support of CHEMOSAT in the treatment of cancers of the liver during the second of half of the year.

"The addition of CHEMOSAT to centers in Spain and Turkey highlight our continued progress commercializing the system in Europe. We continue with negotiations to determine reimbursement levels for CHEMOSAT under the ZE national system in Germany and expect coverage levels to be defined later this year. We believe that favorable reimbursement levels will enhance growth in procedure volumes in Germany and provide important validation for reimbursement appeals in other markets in Europe.

"The advances we made during the first half of 2016 have positioned us to achieve important clinical inflection points in our FOCUS trial and our global Phase 2 program in HCC and ICC, as we work to expand global access to our CHEMOSAT for the benefit of patients suffering with primary and metastatic liver cancers," concluded Dr. Simpson.

**Second Quarter Financial Results**

Total revenues for the second quarter of 2016 and 2015 were $0.5 million. Selling, general and administrative expenses for the second quarter of 2016 were $2.3 million, compared with $2.5 million for the same period in 2016, primarily attributable to a reduction in depreciation and corporate expenses. Research and development expenses increased to $1.9 million for the 2016 second quarter from $1.5 million for the same period in 2015, primarily due to increased investment in clinical development initiatives, specifically the global Phase 3 FOCUS clinical trial.

Total operating expenses for the second quarter of 2016 increased to $4.2 million from $4.0 million for the same period in 2015. This reflects an increase in clinical development initiatives, partially offset by reductions in depreciation and corporate expenses.

The Company recorded a net loss for the three months ended June 30, 2016 of $6.7 million, an increase of $3.0 million from a net loss of $3.7 million for the same period in 2015. This was primarily driven by amortization of debt discounts related to the convertible note issued in June 2016 and a change in the fair value of the warrant liability, a non-cash item.

**First Half Financial Results**

Total revenues for the first half of 2016 and 2015 were $0.9 million. Selling, general and administrative expenses for the first six months of 2016 were $4.7 million, an improvement of $0.8 million or 15% from $5.5 million reported for the same period in 2015, primarily attributable to a reduction in facility expenses related to the lease restructurings. Research and development expenses during the first half of 2016 increased to $3.3 million

compared with $2.4 million for the same period in 2015, primarily due to increased investment in clinical development initiatives.

Total operating expenses for the first half of 2016 were $8.0 million compared with $8.0 million for the same period in 2015.

The Company recorded a net loss for the six months ended June 30, 2016 of $8.5 million, an increase of $1.3 million from a net loss of $7.2 million for the six months ended June 30, 2015. This was primarily driven by amortization of debt discounts related to the convertible note issued in June 2016 and a change in the fair value of the warrant liability, a non-cash item.

**Balance Sheet Highlights**

As of June 30, 2016, Delcath had cash and cash equivalents of $7.5 million, compared with $12.6 million as of December 31, 2015. During the first half of 2016, the Company used $7.0 million in cash to fund its operating activities. In June 2016, Delcath issued $35.0 million of senior convertible notes and related common stock purchase warrants. As a result, Delcath believes it has sufficient capital to fund its operating activities through the end of 2017.

**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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**-Tables to Follow-**

**DELCATH SYSTEMS, INC.**
**Condensed Consolidated Balance Sheets**
*(in thousands, except share data)*

| | June 30, 2016 (Unaudited) | December 31, 2015 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 7,484 | $ 12,607 |
| Restricted cash | 17,162 | — |

| | | |
|---|---|---|
| Accounts receivables, net | 363 | 277 |
| Inventories | 746 | 757 |
| Prepaid expenses and other current assets | 1,245 | 960 |
| Total current assets | 27,000 | 14,601 |
| Restricted cash, net of current portion | 13,100 | — |
| Deferred financing costs, net of current portion | 226 | — |
| Property, plant and equipment, net | 1,062 | 1,132 |
| Total assets | $ 41,388 | $ 15,733 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 439 | $ 284 |
| Accrued expenses | 2,035 | 2,243 |
| Current portion of convertible notes payable, net of discount | — | — |
| Warrant liability | 31,181 | 3,785 |
| Total current liabilities | 33,655 | 6,312 |
| Convertible notes payable, net of current portion and debt discount | 1,568 | — |
| Deferred Revenue | 19 | — |
| Other non-current liabilities | 716 | 820 |
| Total liabilities | 35,958 | 7,132 |
| Commitments and Contingencies | — | — |
| Stockholders' equity | | |
| Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively | — | — |
| Common stock, $.01 par value; 500,000,000 shares authorized; 1,541,016 and 1,396,348 shares issued and 1,521,906 and 1,360,239 shares outstanding at June 30, 2016 and December 31, 2015, respectively | 15 | 14 |
| Additional paid-in capital | 275,182 | 269,863 |
| Accumulated deficit | (269,698) | (261,217) |
| Treasury stock, at cost; 110 shares at June 30, 2016 and December 31, 2015, respectively | (51) | (51) |
| Accumulated other comprehensive income | (18) | (8) |
| Total stockholders' equity | 5,430 | 8,601 |
| Total liabilities and stockholders' equity | $ 41,388 | $ 15,733 |

**DELCATH SYSTEMS, INC.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
**(Unaudited)**
*(in thousands, except share and per share data)*

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Revenue | $ 511 | $ 466 | $ 880 | $ 910 |
| Cost of goods sold | 150 | 137 | 261 | 270 |
| Gross profit | 361 | 329 | 619 | 640 |
| Operating expenses: | | | | |
| Selling, general and administrative | 2,287 | 2,502 | 4,663 | 5,542 |
| Research and development | 1,945 | 1,450 | 3,289 | 2,430 |
| Total operating expenses | 4,232 | 3,952 | 7,952 | 7,972 |
| Operating loss | (3,871) | (3,623) | (7,333) | (7,332) |
| Change in fair value of the warrant liability, net | (1,181) | (48) | 491 | 161 |
| Other income (expense) | (1,615) | (28) | (1,638) | (18) |
| Net loss | $ (6,667) | $ (3,699) | $ (8,480) | $ (7,189) |
| Other comprehensive income (loss): | | | | |
| Foreign currency translation adjustments | (1) | 7 | (10) | (7) |
| Comprehensive loss | $ (6,668) | $ (3,692) | $ (8,490) | $ (7,196) |
| Common share data: | | | | |
| Basic and diluted loss per common share | $ (4.41) | $ (4.84) | $ (5.72) | $ (9.96) |
| Weighted average number of basic and diluted common shares outstanding | 1,510,752 | 765,072 | 1,483,148 | 722,036 |

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