# Delcath Announces Fiscal 2011 Third Quarter Results and Recent Developments

November 7, 2011

**Quarterly Investor Call to be Held Monday November 7, 2011 at 4:30pm ET--**

NEW YORK, Nov. 7, 2011 /PRNewswire via COMTEX/ --

Delcath Systems (NASDAQ: DCTH) today reported financial results for the fiscal 2011 third quarter ended September 30, 2011. Highlights for the quarter and recent developments include:

- **Research & Development:** Accelerated development of Generation Two of the Delcath Hepatic CHEMOSAT® Delivery system, which has demonstrated significantly higher filtration efficiency of melphalan in pre-clinical testing compared to Generation One of the system.
- **European Commercialization:** Submission of CE Mark application for high-efficiency filter of Generation Two CHEMOSAT system, and earlier than anticipated availability of Generation Two for initial launch in European markets in early Q1 2012, subject to CE Mark approval.
- **Establishment of European Business Entity & Headquarters:** Formation of Delcath Systems Ltd. (Delcath Limited), an Irish company headquartered in Galway, Ireland, under which Delcath will conduct its European operations. Delcath Limited received a development grant from IDA Ireland to support the hiring of staff over the next three years.
- **U.S. Regulatory:** Pre-New Drug Application (NDA) meeting scheduled with U.S. Food and Drug Administration (FDA) for mid-January 2012.
- **International Regulatory:** Completion of product notification process for CHEMOSAT with the Medicines and Medical Device Safety Authority in New Zealand, and submission of applications to obtain regulatory approval for CHEMOSAT for several other markets including Australia, Singapore and Hong Kong. The Company also submitted an application to obtain European CE Mark approval for the Generation Two high efficiency filter.
- **Clinical Trial Data Update:** Updated efficacy results from the Company's Phase 3 trial showed the potential for CHEMOSAT as a promising treatment option for patients with metastatic melanoma in the liver, and were presented at the European Multidisciplinary Cancer Congress; Positive Phase 2 trial results from the neuroendocrine tumor cohort showing a 70% overall response rate were presented at the Cardiovascular and Interventional Radiological Society of Europe conference; announced encouraging top-line results for the hepatobiliary cohort and top-line results for metastatic colorectal cohort of the Phase 2 trial.
- **Leadership Team Expansion:** Addition of Graham G. Miao, M.S, MBA, Ph.D., as Executive Vice President, Chief Financial Officer; appointment of David McDonald, to newly created role of Executive Vice President, Business Development
- **Common Stock Offering:** Successfully completed the sale of 5,000,000 shares of common stock in July 2011 for $23.6 million in net proceeds.

"Our company had a productive third quarter, with progress made in several areas toward commercialization of our CHEMOSAT system," said Eamonn P. Hobbs, President and CEO of Delcath. "While some of our goals have yet to be achieved, we are pleased that we will be able to meet emerging interest in CHEMOSAT with faster than expected development of our Generation Two version of the system, which we believe will not only improve filtration efficiency, but potentially lead to new therapeutic possibilities as well. Along with the positive clinical data released during the quarter, these and other developments have positioned us well to begin realizing the potential of the CHEMOSAT system in 2012."

For the three months ended September 30, 2011, the Company's operating loss was $12.2 million, which included approximately $900,000 in non-cash stock-based compensation expense. This compares to an operating loss for the same period in the prior year of $7.4 million, which included approximately $1.4 million in non-cash stock-based compensation expense. General and administrative (G&A) expenses were $5.7 million for the third quarter of 2011, compared to $3.2 million for the same period in the prior year. The increase in G&A was primarily due to an expansion in staff as the Company continued its progress in transitioning from a development stage company to a commercial enterprise and preparations for commercialization in Europe. Research and development (R&D) expenses were $6.4 million for the third quarter of 2011, compared to $4.3 million for the same period in the prior year. The increase in R&D expenses was primarily due to our expanded research and development activities and regulatory expenses related to the preparation of our NDA submission for the FDA.

For the nine months ended September 30, 2011, the Company's operating loss was $30.5 million, which included approximately $3.4 million in non-cash stock-based compensation expense. This compares to an operating loss for the nine months ended September 30, 2010 of $21.2 million, which included approximately $3.9 million in non-cash stock-based compensation expense. G&A expenses were $15.1 million for the nine months ended September 30, 2011, compared to $9.4 million for the nine months ended September 30, 2010. The increase in G&A was primarily due to an expansion in staff as the Company continued its progress in transitioning from a development stage company to a commercial enterprise and preparations for commercialization in Europe. R&D expenses were $15.3 million for the nine months ended September 30, 2011, compared to $11.8 million during the first nine months of 2010. During 2010, the Company was incurring expenses related to wrapping up its Phase III clinical trial. The reduction in trial related expenses during 2011 was more than offset by an increase in expenses related to our expanded research and development activities and regulatory expenses related to our submission to the FDA.

At September 30, 2011, cash, cash equivalents and certificates of deposit were $44.7 million, as compared to $54.3 million at September 30, 2010.

**Conference Call and Webcast**

The Company will host a conference call today, November 7, 2011 at 4:30 p.m. ET, to discuss its recent corporate developments and update its progress. Eamonn Hobbs, President and Chief Executive Officer, will host the call. To participate in the live call by telephone, please dial 800-322-5044 for domestic participants and 617-614-4927 for international participants, both using passcode 65515511. Participants are asked to call the above numbers 5-10 minutes prior to the starting time. To access the live webcast of the call, go to Delcath's website at www.delcath.com.

In addition, a taped replay of the conference call will also be available beginning approximately two hours after the call's conclusion and will be available for seven days. This replay can be accessed by dialing 888-286-8010 for domestic callers and 617-801-6888 for international callers, both using passcode 65413528. An archived webcast will also be available at www.delcath.com.

**About Delcath Systems**

Delcath Systems, Inc. is a development stage specialty pharmaceutical and medical device company focused on oncology. Delcath's proprietary system for chemosaturation 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 concluded a Phase 3 metastatic melanoma study, and the Company recently completed a multi-arm Phase 2 trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Delcath Hepatic CHEMOSAT® delivery system in April 2011. The Company has not yet received FDA approval for commercial sale of its system in the United States. For more information, please visit the Company's website at http://www.delcath.com/.

*The 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 time required to build inventory and establish commercial operations in Europe, CE Marking for the Generation Two system, the timing of our commercial launch in Europe, adoption, use and resulting sales, if any, for CHEMOSAT in the EEA, our ability to successfully commercialize CHEMOSAT and the potential of the chemosaturation therapy as a treatment for patients with cancers in the liver, acceptability of the clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from the FDA and the timing of our re-submission of our NDA, re-submission and acceptance of the Company's NDA by the FDA, approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, approval of the current or future Delcath's system for chemosaturation in the United States and foreign markets for the same or other indications, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for CHEMOSAT, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, uncertainties relating to the results of research and development projects and 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:**

| Investor Contact: | Media Contact: |
|---|---|
| Doug Sherk/Gregory Gin | Janine McCargo |
| EVC Group | EVC Group |
| 415-568-4887/646-445-4801 | 646-688-0425 |


**DELCATH SYSTEMS, INC.**
**(A Development Stage Company)**

**Condensed Consolidated Balance Sheets**
**(Unaudited)**

| | September 30, 2011 | December 31, 2010 |
|---|---|---|
| **Assets:** | | |
| Current assets | | |
| Cash and cash equivalents | $ 40,962,993 | $ 45,621,453 |
| Investments - Certificates of deposit | 3,735,000 | 1,492,000 |
| Prepaid expenses and other assets | 1,028,902 | 1,784,276 |
| Total current assets | 45,726,895 | 48,897,729 |
| Property, plant and equipment | | |
| Land | 154,224 | - |
| Furniture and fixtures | 2,067,289 | 669,296 |
| Computers and equipment | 1,089,398 | 548,586 |
| Leasehold improvements | 1,121,366 | 939,518 |
| | 4,432,277 | 2,157,400 |
| Less: accumulated depreciation | (1,200,798) | (477,420) |
| Property, plant and equipment, net | 3,231,479 | 1,679,980 |
| Total assets | $ 48,958,374 | $ 50,577,709 |
| **Liabilities and Stockholders' Equity:** | | |
| Current liabilities | | |
| Accounts payable | $ 657,929 | $ 610,457 |
| Accrued expenses | 4,377,291 | 2,581,853 |

| | | |
|---|---|---|
| Warrant liability | 3,140,996 | 18,005,014 |
| Total current liabilities | 8,176,216 | 21,197,324 |
| Deferred revenue | 300,000 | 300,000 |
| Commitments and contingencies | - | - |
| Stockholders' equity | | |
| Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding | - | - |
| Common stock, $.01 par value; 70,000,000 shares authorized; 48,232,774 and 43,028,146 shares issued and 47,993,732 and 42,932,460 outstanding at September 30, 2011 and December 31, 2010, respectively | 482,328 | 430,281 |
| Additional paid-in capital | 171,762,847 | 144,782,807 |
| Deficit accumulated during the development stage | (131,671,714) | (116,055,400) |
| Treasury stock, at cost; 28,100 shares at September 30, 2011 and December 31, 2010 | (51,103) | (51,103) |
| Accumulated other comprehensive loss | (40,200) | (26,200) |
| Total stockholders' equity | 40,482,158 | 29,080,385 |
| Total liabilities and stockholders' equity | $ 48,958,374 | $ 50,577,709 |

DELCATH SYSTEMS, INC.
(A Development Stage Company)

**Condensed Consolidated Statements of Operations and Comprehensive Income**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | Cumulative from Inception (Aug 5, 1988) to September 30, |
|---|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 | 2011 |
| **Costs and expenses:** | | | | | |
| General and administrative expenses(1) | $ 5,744,142 | $ 3,165,414 | $ 15,148,228 | $ 9,413,709 | $ 55,013,310 |
| Research and development costs(1) | 6,437,186 | 4,256,048 | 15,333,306 | 11,800,267 | 71,923,470 |
| Total costs and expenses | 12,181,328 | 7,421,462 | 30,481,534 | 21,213,976 | 126,936,780 |
| Operating loss | (12,181,328) | (7,421,462) | (30,481,534) | (21,213,976) | (126,936,780) |
| Change in fair value of warrant liability, net | 3,871,727 | (2,111,543) | 14,864,018 | (10,164,567) | (5,834,584) |
| Interest income | 537 | 2,949 | 1,202 | 6,824 | 2,872,481 |
| Other income and interest expense | - | - | - | - | (274,226) |
| Net loss | (8,309,064) | (9,530,056) | (15,616,314) | (31,371,719) | (130,173,109) |
| Other comprehensive income (loss) | (3,000) | (3,000) | (14,000) | (4,000) | (40,200) |
| Total comprehensive loss | $ (8,312,064) | $ (9,533,056) | $ (15,630,314) | $ (31,375,719) | $ (130,213,309) |
| **Common share data:** | | | | | |
| Basic and diluted loss per share | $ (0.18) | $ (0.24) | $ (0.35) | $ (0.83) | |
| Weighted average number of shares of common stock outstanding, basic and diluted | 46,961,123 | 39,712,207 | 44,315,838 | 37,703,577 | |

Note 1:
Includes non-cash stock-based compensation as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 |
| **Costs and expenses:** | | | | |
| General and administrative expenses | $ 525,250 | $ 879,777 | $ 2,185,473 | $ 2,535,370 |
| Research and development costs | 371,375 | 496,662 | 1,172,678 | 1,404,252 |
| Total stock-based compensation expense | $ 896,625 | $ 1,376,439 | $ 3,358,151 | $ 3,939,622 |

SOURCE Delcath Systems, Inc.