

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): **September 28, 2011 (September 23, 2011)**

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16133
(Commission File Number)

06-1245881
(IRS Employer
Identification Number)

810 Seventh Avenue, 35th Floor, New York, New York, 10019
(Address of principal executive offices, including zip code)

(212) 489-2100
(Registrant's telephone number, including area code)

NONE
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 8.01. Other Events.

On September 23, 2011, Delcath Systems, Inc. issued a press release announcing that updated investigator results from the Phase 3 randomized trial of Delcath's chemosaturation system with melphalan in patients with hepatic metastases from ocular or cutaneous melanoma were presented at the European Multidisciplinary Cancer Congress held in Stockholm, Sweden. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

On September 25, 2011, Delcath Systems, Inc. issued a press release announcing that additional data from the metastatic neuroendocrine tumor (mNET) cohort of Delcath's recently completed Phase 2 clinical trial of its chemosaturation system were presented at the European Multidisciplinary Cancer Congress held in Stockholm, Sweden. A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

The following exhibits are filed herewith:

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Delcath Systems, Inc., dated September 23, 2011
99.2	Press Release of Delcath Systems, Inc., dated September 25, 2011

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DELCATH SYSTEMS, INC.

Dated: September 28, 2011

By: /s/ Peter J. Graham
Name: Peter J. Graham
Title: Executive Vice President,
General Counsel

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Delcath Systems, Inc., dated September 23, 2011
99.2	Press Release of Delcath Systems, Inc., dated September 25, 2011



DELCATH ANNOUNCES UPDATED EFFICACY RESULTS FROM PHASE 3 TRIAL OF CHEMOSATURATION FOR MELANOMA METASTASES IN THE LIVER PRESENTED AT EUROPEAN MULTIDISCIPLINARY CANCER CONGRESS

March 2011 Data Confirm Strong Treatment Effect of Chemosaturation

NEW YORK and STOCKHOLM, SWEDEN, September 23, 2011 – Delcath Systems (NASDAQ: DCTH) announced today that James F. Pingpank, MD, FACS, Associate Professor of Surgery at the University of Pittsburgh School of Medicine, will present updated investigator results from the Phase 3 randomized trial of Delcath's chemosaturation system with melphalan in patients with hepatic metastases from ocular or cutaneous melanoma.

Dr. Pingpank, a lead principal investigator of the Phase 3 trial, will present the abstract (9304), "Percutaneous Hepatic Perfusion (PHP) vs. Best Alternative Care (BAC) for Patients with Melanoma Liver Metastases - Efficacy Update of the Phase 3 Trial," in the plenary session today at 11:15am CEST at the European Multidisciplinary Cancer Congress in Stockholm. These updated results include follow-up data from patients through March 2011, an additional 12 months of data maturation from when Dr. Pingpank first presented investigator data from this Phase 3 trial in June 2010, at the American Society of Clinical Oncology's Annual Meeting.

With respect to the study's primary endpoint of hepatic progression free survival ("hPFS"), the updated investigator-assessed results showed that patients in the chemosaturation arm demonstrated median hPFS of 8.0 months compared to 1.6 months in the BAC arm, a significant 6.4 month extension of hPFS (hazard ratio 0.35, $p < 0.0001$). Median overall PFS in the chemosaturation arm was 6.7 months compared to 1.6 months in the BAC arm, an increase of 5.1 months (hazard ratio 0.36, $p < 0.0001$).

As reported previously, the hepatic response rate in the chemosaturation arm was 34% compared to 2% for the BAC arm. In addition, 52% of patients in the chemosaturation arm achieved stable disease, compared with 27% in the BAC group, giving a tumor growth control rate of 86% for the chemosaturation group versus 29% for the BAC group ($p < 0.001$). Patients who crossed from the BAC arm to chemosaturation treatment after progression of liver disease showed consistent efficacy with patients treated on the chemosaturation arm. As expected, there was no difference in overall survival in the randomized study due to the crossover trial design. An analysis of survival trends by patient cohorts indicated that patients treated with chemosaturation, including crossover

patients, had a median survival of 11.4 months compared to 4.1 months for BAC patients who did not receive chemosaturation. As of June 30th, 11 patients treated with chemosaturation were still alive compared to two patients in the BAC arm who did not receive chemosaturation.

“The additional 12 months of data and extended survival for a significant percentage of the treated patients confirm our belief that chemosaturation may provide a significantly better option than the few treatments presently available for patients with melanoma metastases in the liver,” said Eamonn P. Hobbs, President and CEO of Delcath. “The hepatic PFS, overall PFS and response rate are consistent with past investigator assessments and highly statistically significant. We are encouraged by the data presented in Stockholm today.”

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 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, adoption, use and resulting sales, if any, for the Hepatic CHEMOSAT delivery system in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with terminal metastatic disease in the liver including metastatic melanoma to the liver, acceptability of the Phase III 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 chemosaturation system for other indications, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system, 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:

Doug Sherk/Gregory Gin

EVC Group

415-568-4887/646-445-4801

Media Contact:

Janine McCargo

EVC Group

646-688-0425



DEL CATH ANNOUNCES FURTHER RESULTS FROM NEUROENDOCRINE TUMOR COHORT PRESENTED AT EUROPEAN MULTIDISCIPLINARY CANCER CONGRESS

NEW YORK and STOCKHOLM, SWEDEN, September 25, 2011 –Delcath Systems (NASDAQ: DCTH) announced that James F. Pingpank, MD, FACS, Associate Professor of Surgery at the University of Pittsburgh School of Medicine, will present a poster today that includes additional data from the metastatic neuroendocrine tumor (mNET) cohort of Delcath’s recently completed Phase 2 clinical trial of its chemosaturation system. The poster being presented at the European Multidisciplinary Cancer Congress in Stockholm includes the data previously presented in Dr. Pingpank’s late-breaking abstract at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) congress on September 12, 2011 as well as an additional secondary endpoint of median hepatic progression-free survival (hPFS) of 15.5 months. The mNET cohort is only one of four cohorts in this Phase 2 trial.

In this mNET cohort, 24 patients with unresectable mNET in the liver underwent an average of three chemosaturation procedures with concentrated melphalan and subsequent extra-corporeal venous hemofiltration. Dr. Pingpank will also present the updated hepatic response rate of 70% in 20 evaluable patients, and median overall survival of 30.4 months in all 24 patients on an intent-to-treat basis, as presented at CIRSE. The safety profile of the chemosaturation system remains consistent with that previously reported for the Company’s Phase 3 melanoma trial.

“Currently available treatment options for patients with unresectable neuroendocrine liver metastases have response rates around 5%. The anti-tumor activity, disease control and duration of response seen in the mNET arm of this Phase 2 study is very positive, and suggest a potential role for chemosaturation in this difficult to treat population” said Eamonn P. Hobbs, President & CEO of Delcath. The data presented today add to those presented at CIRSE, and we believe these data affirm the treatment effect of chemosaturation on liver metastases of NET as seen in the Phase 2 study as well as provide a solid efficacy signal in a tumor type other than melanoma. ”

Conducted at the National Cancer Institute (NCI), this Phase 2 clinical trial included four patient cohorts: 1) primary hepatobiliary cancers and metastatic cancers of 2) neuroendocrine, 3) ocular or cutaneous melanoma, and 4) colorectal (adenocarcinoma) origins. Top-line results from the trial’s [hepatobiliary cohort](#) were announced August 22, 2011, and from the [metastatic colorectal cohort](#) on September 1, 2011. The primary objectives were to determine the hepatic response rate and duration of response to intrahepatic infusion of melphalan with subsequent venous hemofiltration. Secondary objective measures included hepatic PFS, overall survival, safety and tolerability.

Delcath has previously described Phase1/2 NCI-led trial results on 23 patients with mNET that were presented at the 2008 American Hepato-Pancreato-Biliary Association annual meeting.

These results included patients from a Phase 1 trial with patients that been enrolled in the Phase 2 trial up to that time. The neuroendocrine cohort of the current, completed Phase 2 trial consisted of 24 patients, all of whom were enrolled in the Phase 2 trial.

About mNET

Neuroendocrine tumors (NETs) are a group of malignant tumors that originate from intersections of the nervous system and endocrine (glandular) system throughout the body and are found in various locations, such as the pancreas, thyroid, lungs, gastrointestinal tract and biliary system. An estimated 9,000 patients in Europe are diagnosed annually with neuroendocrine tumor metastases in the liver, which is the most common site for neuroendocrine tumors to metastasize. Surgery is an accepted treatment for mNETs, but the type and extent of surgery for liver metastasis is contingent upon tumor size and distribution, disease progression, site of origin and other factors including the age and health of the patient. Recently published data from the control arms of randomized controlled trials in pancreatic NET show that progression-free survival is of the order of 6 months without treatment.

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 III metastatic melanoma study, and the Company recently completed a multi-arm Phase II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the 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, adoption, use and resulting sales, if any, for the Hepatic CHEMOSAT delivery system in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with terminal metastatic disease in the liver including mNET, acceptability of the Phase III 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 chemosaturation system for other indications, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system, 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:
Doug Sherk/Gregory Gin
EVC Group
415-568-4887/646-445-4801

Media Contact:
Janine McCargo
EVC Group
646-688-0425