# 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 6, 2011 (September 1, 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, Suite 3505, 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 1, 2011, Delcath Systems, Inc. issued a press release announcing top-line results from the metastatic
colorectal (adenocarcinoma) cohort of the Phase II clinical trial of the Delcath chemosaturation system with melphalan in the
treatment of patients with unresectable liver cancer. 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.

The following exhi	pit is filed herewith:
(d) Exhibits.	
Exhibit No.	Description Press Release of Delcath Systems Inc. dated September 1, 2011

Item 9.01. Financial Statements and Exhibits.

#### **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 6, 2011 By: /s/ Peter J. Graham

Name: Peter J. Graham

Title: Executive Vice President, General Counsel

# EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release of Delcath Systems, Inc., dated September 1, 2011



# DELCATH ANNOUNCES TOP-LINE RESULTS FROM METASTATIC COLORECTAL COHORT IN PHASE II TRIAL OF CHEMOSATURATION SYSTEM

Confirms Plans to Initiate New Phase II Single-Arm Study of Patients with Metastatic Colorectal Cancer of the Liver in 2012

NEW YORK, NY – September 1, 2011 -- Delcath Systems, Inc. (NASDAQ: DCTH) reported top-line results from the metastatic colorectal (adenocarcinoma) cohort of the Phase II clinical trial of the Delcath chemosaturation system with melphalan in the treatment of patients with unresectable liver cancer. The Company also confirmed plans to initiate a new Phase II single-arm study in the second half of 2012. The new study is intended to evaluate the efficacy of Delcath's chemosaturation system and its next-generation high efficiency filter in patients with colorectal cancer that is metastatic to the liver and is refractory to first line systemic chemotherapy.

The recently completed Phase II study, conducted at the National Cancer Institute (NCI) in the U.S., included four patient cohorts: hepatobiliary cancers, and metastatic cancers of neuroendocrine, ocular or cutaneous melanoma, and colorectal (adenocarcinoma) origins. Sixteen patients with very late stage colorectal cancer liver metastases were recruited into this arm. The predominant accrual of very late stage patients reflects the changing referral and treatment patterns at the NCI at the time that this study was conducted, but it was not a design feature of the study. No significant responses were noted among these patients as they had been heavily pre-treated with numerous chemotherapeutic and regional modalities that, along with anatomical and disease-related factors in a few, prevented sufficient melphalan exposure. The safety profile of the chemosaturation system was consistent with that previously reported for the Company's Phase 3 melanoma trial.

"While the efficacy signal from this study was inconclusive due to the factors mentioned above, we believe there is solid clinical and scientific justification to conduct a new Phase II trial in a well-defined metastatic colorectal ("mCRC") patient population who are likely to benefit from chemosaturation with percutaneous hepatic perfusion. Surgical isolated hepatic perfusion with melphalan has previously shown encouraging responses in a well-defined patient population with earlier stage CRC liver metastases. Additionally, our recent *in vitro* experiments evaluating colorectal tumor cell lines that were exposed to melphalan at concentrations achieved during chemosaturation, showed encouraging signals of cell-death induction. As such, we will continue to study the efficacy of our chemosaturation system in this patient population that currently has few treatment options," said Eamonn P. Hobbs, President and CEO of Delcath System, Inc.

Delcath has previously reported encouraging top-line results from the metastatic neuroendocrine and hepatobiliary cohorts of this Phase II trial. Detailed results from the metastatic neuroendocrine arm of this trial will be presented at the Cardiovascular and Interventional Radiological Society of Europe and European Society for Medical Oncology scientific meetings in September.

## **About Colorectal Cancer**

Colorectal cancer is the fourth most common cancer in men and women in the United States, with more than 150,000 new patients diagnosed each year. Approximately 750,000 new cases are diagnosed annually worldwide. It is more common in people over 50, and the risk increases with age. Survival is directly related to stage at detection and the type of cancer involved, but overall is poor for symptomatic cancers, as they are typically quite advanced. Survival rates for early stage detection are approximately five times those of late stage cancers. Stage IV colorectal cancer consists of liver metastases that have spread there from the colon or rectum. In general, approximately 8-15% of people with Stage IV colon cancer are still alive five years after their diagnosis.

### **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, 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, uncertainties relating to the success of future clinical trials, including CRC metastatic to the liver, uncertainties regarding the effectiveness of the chemosaturation system as a treatment for CRC metastatic to the liver, 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