# 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): February 2, 2012

## **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):

[]	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))

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

## Item 8.01. Other Events.

On February 2, 2012, Delcath Systems, Inc. (the "Company") issued a press release announcing that the first patients in Europe have been treated with the Delcath Hepatic CHEMOSAT® Delivery System at the European Institute of Oncology (Instituto Europeo di Oncologia – IEO), a premier cancer treatment and research center in Milan. 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.

In addition, the Company is currently negotiating the terms of a \$20 million credit facility. The Company expects to enter into a definitive agreement with a commercial bank in the first quarter of 2012.

The following exhibits are filed herewith:		
(d) Exhibits.		
Exhibit No.	Description	
99.1	Press Release of Delcath Systems, Inc., dated February 2, 2012	

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: February 2, 2012 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 February 2, 2012



### DELCATH ANNOUNCES FIRST EUROPEAN CHEMOSAT PROCEDURES

## Procedures Conducted At European Institute of Oncology Signals Significant Step Forward In Commercialization of the CHEMOSAT Delivery System to Treat Cancers in the Liver

NEW YORK, February 2, 2012 – Delcath Systems, Inc. (NASDAQ: DCTH) announced today that the first patients in Europe have been treated with the Delcath Hepatic CHEMOSAT® Delivery System at the European Institute of Oncology (Instituto Europeo di Oncologia – IEO), a premier cancer treatment and research center in Milan. The cases were treated as part of the initial launch and training agreement the Company announced with the IEO in November 2011.

Two patients were treated for inoperable liver-dominant metastases from ocular melanoma and gastric cancer. All CHEMOSAT procedures were successfully completed without procedure-related complications. Delcath and the IEO will host a joint-press conference, on February 15, 2012 at the IEO, at which time an update on patient status will be presented.

The procedures were conducted with the Generation One version of the CHEMOSAT system, while the Generation Two version is under review for CE Mark approval by the Notified Body.

"The CHEMOSAT system represents an important advancement in treatment options for cancers in the liver, which have significantly poorer survival rates compared to cancers that have spread predominantly to other organs," said Dr. Alessandro Testori, a surgical oncologist and Director of the Division of Melanoma and Skin-Muscle Sarcoma at the IEO. "We believe this technology will help fill an important gap in the treatment of multiple tumor types in the liver because of its demonstrated ability to deliver concentrated doses of chemotherapeutic agent directly to the liver while helping to minimize systemic exposure. We are pleased to be the first center in Europe to begin offering this treatment to patients and look forward to exploring its potential with Delcath."

CHEMOSAT is a proprietary product that utilizes chemosaturation technology, a minimally invasive, repeatable procedure that delivers high doses of chemotherapeutic drugs directly to the liver while minimizing systemic exposure of such drugs. CHEMOSAT received CE Mark in April 2011 as a Class III medical device with an indication for the percutaneous intra-arterial administration of a chemotherapeutic agent (melphalan hydrochloride) to the liver.

"Since obtaining our CE Mark, Delcath has been committed to supporting the technology in the substantial international liver cancer market," said Eamonn P. Hobbs, President and CEO of Delcath. "These cases represent the first uses of CHEMOSAT outside of a clinical trial—an exciting milestone for Delcath. There is no greater endorsement for CHEMOSAT than to have the first European patients treated at an organization as prestigious as the IEO. We are delighted that the procedures were successfully performed, and look forward to continued collaborative

progress with the IEO and the opportunity to open additional CHEMOSAT treatment centers across Europe."

#### **About the IEO**

The European Institute of Oncology was established in 1994 to implement an innovative model for health and advanced research in the international oncology field. The IEO's mission is focused on state-of-the-art cancer research and treatment, from basic laboratory research that grapples with the genetic roots of cancer, to advanced clinical research such as testing new drugs, all with the unifying goal of finding ways to treat patients more effectively.

### **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 <a href="http://www.delcath.com/">http://www.delcath.com/</a>.

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 future use of the CHEMOSAT delivery system by IEO and future patient outcomes, 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, CE Mark approval for Generation Two of the CHEMOSAT delivery system, 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, resubmission 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:**

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