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): **August 15, 2012**

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-16133	06-1245881
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 August 15, 2012, Delcath Systems, Inc. (the "Company") issued a press release announcing that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration seeking approval for the Company's proprietary chemosaturation system for use with melphalan hydrochloride in the treatment of patients with unresectable metastatic melanoma in the liver. 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.

Item 9.01. Financial Statements and Exhibits.

The following exhibits are filed herewith:

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Delcath Systems, Inc., dated August 15, 2012

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: August 15, 2012

By: /s/ Barbra C. Keck
Name: Barbra C. Keck
Title: Vice President, Controller

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Delcath Systems, Inc., dated August 15, 2012

Exhibit 99.1

DELCATH SUBMITS NEW DRUG APPLICATION FOR PROPRIETARY CHEMOSATURATION SYSTEM TO THE U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK, NY – August 15, 2012 – Delcath Systems, Inc. (NASDAQ: DCTH) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration seeking approval for the Company's proprietary chemosaturation system for use with melphalan hydrochloride in the treatment of patients with unresectable metastatic melanoma in the liver. The Company included its Generation 2 filter in its NDA submission as a technical change to the Chemistry, Manufacturing, and Control (CMC) module.

“Our team has achieved a significant milestone with the filing of our NDA,” said Eamonn P. Hobbs, President and CEO of Delcath Systems. “We believe that our chemosaturation system provides the opportunity to satisfy a high unmet medical need to treat patients with unresectable metastatic melanoma in the liver. We also believe including our Generation 2 filter in the CMC module represents the fastest regulatory review path for the Generation 2 system, and that it is in the best interest of U.S. patients that we accelerate the potential availability of Generation 2.”

“We have requested priority review of our NDA by the FDA. Assuming the NDA is accepted and that priority review is granted, our expected Prescription Drug User Fee Act (PDUFA) date would be in February of next year. Based upon the strength of our Phase 1, 2 and 3 data, along with the limited treatment options available for patients with unresectable melanoma metastases in the liver, we believe that our application meets the FDA's criteria for priority review.”

In Delcath’s Phase 3 clinical trial (April 2010 data cutoff), comparing treatment with the Company’s proprietary chemosaturation system to best alternative care (BAC) revealed that patients treated with chemosaturation therapy experienced a statistically significant extension in median hepatic progression free survival (hPFS) of 5.4 months ($p=0.0001$, hazard ratio 0.39) longer than patients treated with BAC according to independent review committee (IRC) blinded intent-to-treat (ITT) analysis. Previously reported investigator ITT analysis of these data showed an extension in median hPFS of 6.4 months ($p<0.0001$, hazard ratio 0.28) longer than patients treated with BAC. Priority review is granted by the FDA to those products that address significant unmet medical needs or have the potential to provide significant improvement compared to marketed products. The FDA has previously granted Delcath two orphan drug designations for melphalan in ocular and cutaneous melanoma, which will provide the Company with exclusivity in these indications for seven years if the NDA is accepted, reviewed and approved.

About Delcath Systems

Delcath Systems, Inc. is a 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 announced that its randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company also 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 and for its Generation 2 hemofiltration cartridge for CHEMOSAT in April 2012. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe. The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company continues with preparations to further support its NDA submission and intends to seek FDA approval for commercial sale of its chemosaturation system with melphalan. For more information, please visit the Company's website at www.delcath.com.

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: acceptance of the Company's new drug application (NDA) including the Generation 2 filter, the FDA's granting of our request for priority review, the timing of a PDUFA date, acceptability of the Phase 1, 2 and 3 clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from 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, the benefits of the Generation 2 CHEMOSAT system and market acceptance of the same, patient outcomes using the Generation 2 system, the timing of the supply and distribution of the CHEMOSAT system to early launch centers in Europe, 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, 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, acceptance of our IND amendment, the timing and use, if any, of the line of credit from SVB, and our ability to access this facility, 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.

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