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): December 5, 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 December 5, 2012, Delcath Systems, Inc. issued a press release announcing that after recent discussions with the U.S. Food & Drug Administration (FDA), management has elected to modify the label indication it is seeking in its New Drug Application (NDA) for its proprietary chemosaturation system with melphalan hydrochloride for injection to focus on the treatment of patients with unresectable metastatic ocular 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 exhibit is filed herewith:

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Delcath Systems, Inc. dated December 5, 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: December 5, 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 December 5, 2012

FOR RELEASE AT 4:20PM ET 12/5/12

DELCATH PROVIDES UPDATE ON
NDA SUBMISSION FOR ITS CHEMOSATURATION SYSTEM

Webcast Today at 5:00 P.M. ET

NEW YORK, NY – December 5, 2012 — Delcath Systems, Inc. (NASDAQ: DCTH) announced today that after recent discussions with the U.S. Food & Drug Administration (FDA), management has elected to modify the label indication it is seeking in its New Drug Application (NDA) for its proprietary chemosaturation system with melphalan hydrochloride for injection.

Although the Company's Phase 3 trial demonstrated a very positive signal in patients with liver dominant cutaneous melanoma, based upon a recommendation from the FDA, Delcath has decided to focus the Company's NDA indication on the treatment of patients with unresectable metastatic ocular melanoma in the liver. This decision is primarily due to the fact that 90% of the patients enrolled in the Company's Phase 3 trial had ocular melanoma metastases to the liver and the statistically significant efficacy data generated in the trial for this disease. Additionally, FDA-approved treatment options have evolved significantly for metastatic cutaneous melanoma over the past several years, while treatment options for unresectable metastatic ocular melanoma continue to be lacking. Given these facts, the Company believes that its data in ocular melanoma metastases in the liver, coupled with the large unmet need for treatments for this disease, presents the most compelling case for the Company's NDA. The Company hopes that a timely approval of its Chemosaturation system will represent an important step to bring benefits to those cancer patients afflicted with the disease.

"We are very appreciative of the FDA's interest in our NDA and the progress made to date towards our June 15th 2013 PDUFA goal date," said Eamonn P. Hobbs, President & CEO of Delcath Systems. "Assuming our NDA is approved, we believe our decision to focus the initial labeling of our proprietary chemosaturation system on ocular melanoma, where there is a significant unmet medical need, will have little impact on the Chemosaturation system's revenue potential in the U.S., where physicians typically prescribe cancer treatment options based on clinical data and medical professional experience.

"We plan to initiate clinical studies in 2013 to study the use of our chemosaturation system in other tumor types that potentially represent significant commercial opportunities beyond the ocular metastatic melanoma market. Currently, we intend to pursue studies to support label expansion for the use of our system to treat hepatocellular carcinoma and neuroendrocrine cancer patients, and depending on feedback from the FDA could potentially enroll our first patients before the end of 2013."

Webcast Details

The Company will host a webcast today at 5:00 p.m. ET to discuss recent corporate developments, followed by a question-and-answer session. Webcast listeners will have the opportunity to submit questions to management during the live webcast. Select questions will be summarized and addressed during the question-and-answer portion of the call.

The live webcast of the conference call will be available on the Events & Presentations page on the Investor Relations section of Delcath's website at http://www.delcath.com/investors/events/. Webcast participants may submit questions electronically via the webcast interface. For those unable to listen to the live webcast, an archived webcast replay will be available at http://www.delcath.com/investors/events/ beginning approximately two hours after the completion of the live call and will be available for two weeks.

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 Generation Two CHEMOSAT® delivery system for melphalan hydrochloride in April 2012. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system for melphalan hydrochloride in Europe. In October 2012, the Company satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin hydrochloride injection, providing a regulatory pathway for the CHEMOSAT Delivery System to deliver and filter doxorubicin for countries in Asia that accept the CE Marking as part of their national regulatory requirements. The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company's NDA has been accepted for filing and substantive review by the FDA. 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: the impact, if any, of the change in the indication in our NDA and approval of the same, timing of completion of the FDA's review of our NDA, the extent to which the FDA may request additional information or data and our ability to provide the same in a timely manner, acceptability of the Phase 1, 2 and 3 clinical trial data by the FDA, FDA approval of the Company's NDA for the treatment of ocular metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filte melphalan in the EEA, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation system as a treatment for patients with primary and metastatic disease in the liver, market acceptance of the Gen Two CHEMOSAT system and patient outcomes using the same, approval of the current or future chemosaturation system for delivery and filtration of melphalan, doxorubicin or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets including Australia and key Asian markets and timing an revenue, if any, of the same, the approval of the Hepatic CHEMOSAT Delivery System device to deliver and filter doxorubicin in key Asian markets and patient outcomes using the same, our ability to obtain reimbursement for the CHEMOSAT system, uncertainties relating to the timing and results of research and development projects, uncertainties relating to the timing and results of 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.

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