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): November 1, 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 November 1, 2012, Delcath Systems, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013, for substantive review of the Company's New Drug Application ("NDA") for its proprietary chemosaturation system with melphalan hydrochloride for injection. The FDA accepted the Company's NDA submission for filing on October 14, 2012, and designated the NDA for standard review.

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 November 1, 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: November 1, 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 November 1, 2012

DELCATH ANNOUNCES JUNE 15, 2013 PDUFA GOAL DATE FOR NEW DRUG APPLICATION

NEW YORK, November 1, 2012 – Delcath Systems, Inc. (NASDAQ: DCTH) announced today that the U.S. Food and Drug Administration (FDA) assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013, for substantive review of the Company's New Drug Application (NDA) of its proprietary chemosaturation system with melphalan hydrochloride for injection.

The FDA accepted Delcath's NDA submission for filing on October 14, 2012, and designated the NDA for standard review.

The Company seeks approval to market and sell its proprietary chemosaturation system with melphalan hydrochloride in the United States as a treatment for patients with unresectable metastatic melanoma in the liver.

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 with melphalan hydrochloride for injection in April 2011 and for the second generation hemofiltration cartridge for CHEMOSAT with melphalan hydrochloride for injection 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's NDA has been accepted for filing and substantive review by the FDA. The Company is seeking approval for its proprietary chemosaturation system with melphalan hydrochloride as a treatment for patients with unresectable metastatic melanoma in the liver.

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 contents of the 74 Day letter and our ability to address 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 metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, patient outcomes using the Generation 2 system, 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 strategic partnerships in foreign markets including in key Asian markets and timing of the same, the initiation of clinical trials in key Asian markets with the CHEMOSAT system for doxorubicin and timing and results of the same, approval of the CHEMOSAT system with doxorubicin in key Asian markets, patient outcomes using the CHEMOSAT system with doxorubicin, 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.

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