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 13, 2013**

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)

566 Queensbury Avenue, Queensbury, New York, 12804
(Address of principal executive offices, including zip code)

(518) 743-8892
(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 13, 2013, Delcath Systems, Inc. (“Delcath”) issued a press release announcing that it has received a "Complete Response" letter from the U.S. Food & Drug Administration for the New Drug Application for Delcath’s Melblez™ Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) for the treatment of patients with unresectable ocular melanoma metastatic to 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 September 13, 2013

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 13, 2013

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 13, 2013

DELCATH RECEIVES COMPLETE RESPONSE LETTER FROM FDA FOR MELBLEZ™ KIT NEW DRUG APPLICATION

NEW YORK, NY – September 13, 2013 – Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) received September 12, 2013 regarding the New Drug Application (NDA) for Delcath's Melblez™ Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) for the treatment of patients with unresectable ocular melanoma metastatic to the liver.

A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes approval of the NDA in its current form. The FDA comments included a statement that Delcath must perform another "well-controlled randomized trial(s) to establish the safety and efficacy of Melblez Kit using overall survival as the primary efficacy outcome measure," and which "demonstrates that the clinical benefits of Melblez Kit outweigh its risks." In addition to the FDA requirement to conduct an additional clinical trial(s) using the product the Company intends to market, Delcath is evaluating the other requirements contained in the letter, and will review potential regulatory paths forward with the FDA.

About Delcath Systems

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product, the Delcath Hepatic Delivery System, is designed to administer high dose chemotherapy and other therapeutic agents to the liver, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers. Outside of the United States, our proprietary product to deliver and filter melphalan hydrochloride is marketed under the trade name Delcath Hepatic CHEMOSAT® Delivery System for melphalan hydrochloride. The Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan in April 2012. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT Delivery System for Melphalan in Europe. In addition, the Company has initiated plans to investigate the Melblez Kit for primary liver cancer. 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 Company's ability to satisfy the requirements of the FDA's Complete Response Letter and provide the same in a timely manner, adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter 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 and 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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