# 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): **April 08, 2013 (April 08, 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) |

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 April 8, 2013, Delcath Systems, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has extended the initial Prescription Drug User Fee Act ("PDUFA") goal date for its review of the Company's New Drug Application (the "NDA") for the marketing approval of Melblez™ Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), the Company's proprietary drug/device combination product for the treatment of patients with unresectable ocular melanoma metastatic to the liver. The previously announced Oncologic Drugs Advisory Committee ("ODAC") meeting remains unchanged, and the FDA will convene its ODAC Panel on Thursday, May 2, 2013 for review of the Company's NDA.

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 April 8, 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: April 8, 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 April 8, 2013 |

**Exhibit 99.1**

**DELCATH RECEIVES NOTIFICATION OF PDUFA DATE EXTENSION**

*New PDUFA Goal Date is September 13, 2013*
*ODAC meeting remains May 2, 2013*

**NEW YORK, NY – April 8, 2013** – Delcath Systems, Inc. (NASDAQ: DCTH) today announced that the U.S. Food and Drug Administration (FDA) has extended the initial Prescription Drug User Fee Act (PDUFA) goal date for its review of the Company's New Drug Application (NDA) for the marketing approval of Melblez™ Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), the Company's proprietary drug/device combination product for the treatment of patients with unresectable ocular melanoma metastatic to the liver.

On March 18, 2013 the Company supplied certain information in response to an FDA request. The information related to clarification regarding the bridging studies that were performed between the filter generations that were used throughout the development program. As the information was requested and supplied within 90 days of the June 15, 2013 PDUFA goal date, the agency exercised its option to extend the PDUFA goal date to provide adequate time for completion of its review. The three-month extension to September 13, 2013 is the standard extension cycle granted.

The previously announced Oncologic Drugs Advisory Committee (ODAC) meeting remains unchanged, and the FDA will convene its ODAC Panel on Thursday, May 2, 2013 for review of the Company's NDA.

***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 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. 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 (CHEMOSAT Delivery System for Melphalan.) 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

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 (CHEMOSAT Delivery System for Doxorubicin). 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: 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, additional extensions to the PDUFA date by the FDA, the outcome of the ODAC meeting, and the impact, if any, of the advisory panel's recommendation on the FDA's decision regarding the Company's new drug application (NDA), 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 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 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.*

**Contact Information:**

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