DELCATH SYSTEMS INC
Form 8-K
April 08, 2013

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 MelblezTM 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

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