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): **February 22, 2011**

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, Suite 3505, 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 February 22, 2011, Delcath Systems, Inc. issued a press release announcing that it has received a "refusal to file" letter from the U.S. Food & Drug Administration for the New Drug Application for its proprietary chemosaturation system used in the treatment of patients with metastatic melanoma in the liver through the percutaneous intra-arterial administration of melphalan hydrochloride. It also announced the CE Mark Technical File review process for marketing approval of the Hepatic ChemoSAT™ Delivery System continues on schedule and provided certain information on its cash position. 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 February 22, 2011

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: February 22, 2011

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 February 22, 2011

DELCATH SYSTEMS RECEIVES REFUSAL TO FILE LETTER FROM FDA

Intends to Resubmit NDA by September 30, 2011

European CE Mark Technical File Review Process Continues on Schedule

NEW YORK, February 22, 2011 -- Delcath Systems, Inc. (NASDAQ: DCTH) announced today that the Company has received a "refusal to file" letter from the U.S. Food & Drug Administration (FDA) for the New Drug Application (NDA) for its proprietary chemosaturation system used in the treatment of patients with metastatic melanoma in the liver through the percutaneous intra-arterial administration of melphalan hydrochloride. Delcath expects to submit a formal meeting request to the FDA this week and intends to meet with the FDA at the earliest opportunity to discuss the issues raised and to confirm our understanding of the remedies required for the filing t o be accepted. Based on management's current understanding of the information in the FDA's letter, the Company intends to resubmit the NDA by September 30, 2011.

In accordance with application regulations, the FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission, which occurred on December 22, 2010. Neither the acceptance nor non-acceptance of the NDA filing is a determination of the approvability of the chemosaturation system.

"The FDA's letter requested information involving manufacturing plant inspection timing, product and sterilization validations and additional safety information that we already planned on filing with our 120 day safety update in April, as well as additional statistical analysis clarification," said Eamonn P. Hobbs, CEO & President of Delcath Systems. "We believe that we will be able to provide the requested information in an updated application and we expect to resubmit the NDA by the end of the third quarter of this year. In the meantime, the CE Mark Technical File review process for marketing approval of the Hepatic ChemoSAT™ Delivery System continues on schedule. Our expectation remains that we will be able to begin addressing the significant European market opportunity by mid-year."

Delcath had a cash position of approximately $47 million as of December 31, 2010. The Company's monthly cash burn rate continues to be approximately $2.2 million per month. As Delcath plans for the anticipated European commercial launch of the Hepatic ChemoSAT Delivery System in the second half of 2011, the Company expects the monthly burn rate will rise in the coming quarters.

Conference Call Information

Delcath will host a conference call today, February 22, 2011 at 8:30 a.m. Eastern Time. Eamonn Hobbs, President and Chief Executive Officer, and David McDonald, Chief Financial Officer, will host the call. The dial-in number for the conference call is 1-877-941-1465 for domestic participants and 1-480-629-9644 for international participants. An audio replay of the call will be available for seven days following the call, and can be accessed by dialing 1-800-406-7325 for domestic callers and 303-590-3030 for international callers, both using passcode 4417144#. The call will also be available on the Internet live and for 7 days thereafter at www.delcath.com.

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 concluded a Phase III metastatic melanoma study, and the Company recently completed a multi–arm Phase II trial to treat other liver cancers. The Company has not yet received FDA or any foreign regulatory approval for commercial sale of its system. For more information, please visit the Company's website at www.delcath.com.

The 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 acceptability of the Phase III clinical trial data by the FDA, our ability to address the questions raised in the FDA's refusal to file letter and re-submit an NDA by the end of our third quarter, acceptance of the Company's NDA by the FDA, approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales i n the United States, acceptance of the Company's CE Mark Technical File by its Notified Body, receipt of CE Mark approval, adoption, use and resulting sales in the EU, if any, 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 regulatory agencies, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, 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 t o publicly update or revise these forward–looking statements to reflect events or circumstances after the date they are made.

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