

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): May 11, 2005

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-16133 (Commission File Number)	06-1245881 (IRS Employer Identification No.)
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1100 Summer Street, Stamford, Connecticut 06905
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (203) 323-8668

N/A
(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))

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Section 8 - Other Events

Item 8.01 Other Events.

On May 11, 2005, Delcath Systems, Inc. (the "Company") issued a press release relating to the Company's system for delivering high dose chemotherapy to specific organs and body regions has received fast-track status from the U.S. Food and Drug Administration for treating metastatic melanoma in the liver with melphalan. The Company's press release dated May 11, 2005 is incorporated herein by reference and filed as an exhibit hereto.

Section 9 - Financial Statements and Exhibits

Item 9.01 Financial Statements and Exhibits.

- (a) Not applicable
- (b) Not applicable.
- (c) Exhibits:

Exhibit	Description
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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.

By: /s/ M. S. KOLY

M. S. Koly
President and Chief Executive
Officer

Date: May 11, 2005

EXHIBIT INDEX

Exhibit	Description
99	Press Release dated May 11, 2005 of Delcath Systems, Inc.

Delcath Receives Fast-Track Status from U.S. FDA for High Dose Cancer Treatment with Melphalan

STAMFORD, Conn., May 11, 2005 -- Delcath Systems, Inc. (DCTH) said its novel system for delivering high dose chemotherapy to specific organs and body regions received fast-track status from the U.S. FDA for treating metastatic melanoma in the liver with melphalan, a currently approved anticancer agent.

The FDA decision was reached following the recent meeting at which the company and National Cancer Institute (NCI) researchers presented the results from the initial clinical trial which Delcath sponsored at the NCI. While the trial was not designed to prove efficacy, and the numbers were too low to make any statistical claims, the NCI study demonstrated reductions in the size of melanoma tumors in the liver of some of the patients treated with the Delcath system.

The FDA's fast-track program is designed to facilitate development and expedite the review of new drugs or, in the case of Delcath, a new drug-device combination, having the potential to treat illnesses which currently lack adequate therapy.

In its official notification to Delcath, the FDA letter stated:

"Melanoma, metastatic to the liver, is a serious or life-threatening disease. New treatment methods that can induce disease remission will be an important addition to the current treatment armamentarium."

It went on to say:

"The Delcath drug delivery system allows for intrahepatic perfusion with high doses of the chemotherapy drug melphalan followed by extracorporeal venous filtration to lower systemic exposure to melphalan. High intrahepatic melphalan concentrations may cause greater tumor regression than standard dose treatment."

The benefits of the FDA's fast-track program include closer and more frequent interactions with the agency during development and can lead to an expedited review of approval applications.

"This is the single most important event for Delcath since going public five years ago. It is also of potential importance to patients diagnosed with inoperable melanoma in the liver, for whom existing treatment options are extremely limited and unsuccessful," said M.S. Koly, Delcath's Chief Executive Officer.

About Delcath

Delcath is a developer of isolated perfusion technology for organ or region-specific delivery of therapeutic agents. Six U.S. and three foreign issued patents cover its technology. The company is headquartered in Stamford, CT.

This release contains "forward-looking statements" based on current expectations but involving known and unknown risks and uncertainties. Actual results or achievements may be materially different from those expressed or implied. Delcath plans and objectives are based on assumptions involving judgments with respect to future economic, competitive and market conditions, its ability to consummate, and the timing of, acquisitions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond its control. Therefore, there can be no assurance that any forward-looking statement will prove to be accurate.

Please read carefully. This material contains "forward-looking statements" based on current expectations which involve known and unknown risks and uncertainties. Actual results or achievements may be materially different from those expressed or implied. Any plans or objectives expressed herein are based on assumptions involving judgments with respect to future economic, competitive and market conditions, the timing or consummation of acquisitions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond its control. Therefore, there can be no assurance that any forward-looking statement will prove to be accurate. Redington acts as subject company's paid investor relations counsel and its employees or members of their families may own securities in subject company.
