

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): February 7, 2006

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 (Address of principal executive offices)	06905 (Zip Code)
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Registrant's telephone number, including area code: (203) 323-8668

N/A  
(Former name or former address, if changes 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 February 7, 2006, Delcath Systems, Inc. (the "Company") issued a press release relating to the approval by the Institutional Review Board of the National Cancer Institute of a Phase III clinical trial using the Company's technology to deliver high dosages of melphalan for treatment of metastatic melanoma in the liver. The Company's press release dated February 7, 2006 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) Not applicable.
- (d) Exhibits:



## 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

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M. S. Koly  
President and Chief Executive  
Officer

Date: February 7, 2006

Contact:

Delcath Systems, Inc.  
M. S. Koly, Chief Executive Officer  
203-323-8668  
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Delcath Systems Receives NCI Institutional Review Board Approval

STAMFORD, Conn., February 7, 2006 -- Delcath Systems, Inc. (Nasdaq: DCTH), today announced the National Cancer Institute (NCI) Institutional Review Board (IRB) has approved the Company's pivotal Phase III clinical trial for the treatment of metastatic melanoma in the liver with melphalan, an approved anticancer agent.

With IRB approval, Delcath and the NCI will be able to initiate the recruitment of patients for its Phase III clinical trial immediately following the U.S. Food and Drug Administration (FDA) protocol approval. In May 2005, the FDA granted fast-track status for the company's Phase III clinical trial. By scheduling the Phase III trial to start after receiving the FDA's protocol approval, Delcath will maintain its eligibility for Special Protocol Assessment (SPA) status, a written agreement that allows Delcath to receive official FDA evaluation on its Phase III trials that form the basis of final FDA approval.

The Delcath system delivers high-dose chemotherapy directly to the liver via the hepatic artery. As blood exits the liver, special Delcath filters trap the chemotherapy, protecting the rest of the body from excessive toxicity. The procedure is repeatable and is less invasive than traditional surgical ways of performing isolated perfusion to effect dose-directed therapy of specific body organs or regions.

M.S. Koly, President and Chief Executive Officer of Delcath Systems, stated, "We are pleased with the decision of NCI's IRB to approve our Phase III study. This approval will help us quickly initiate the trial at the NCI once we receive final protocol approval from the FDA. Our plan is to receive the SPA prior to commencing our Phase III trial in order to take full advantage our FDA fast-track status.

"Delcath continues to enhance its strategic position leading up to its Phase III clinical trial. In addition to IRB approval, recently we increased our financial strength through exercise of outstanding warrants and completion of a \$2.5 million private placement. We believe this additional capital solidifies our ability to execute our Phase III trial at multiple centers throughout the approval process."

About Delcath Systems, Inc.

Delcath Systems is a developer of isolated perfusion technology for organ or region-specific delivery of therapeutic agents. The company's intellectual property portfolio currently consists of 12 patents on a worldwide basis, including the United States, Europe, Asia and Canada.

For more information, please visit the Company's website, [www.delcath.com](http://www.delcath.com).

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's 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 than any forward-looking statement will prove to be accurate.

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