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 22, 2006

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 No.)

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 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))

Section 8 - Other Events

Item 8.01 Other Events.

On February 22, 2006, Delcath Systems, Inc. (the "Company") issued a press release relating to the completion of a Special Protocol Assessment and Agreement with the U.S. Food and Drug Administration. The Company's press release dated February 22, 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:

Exhibit	Description

99 Press Release dated February 22, 2006 of Delcath Systems, Inc.

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: February 22, 2006

[LOGO]

FOR IMMEDIATE RELEASE

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Delcath Systems Receives Special Protocol Assessment and Agreement from FDA

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Company to Commence Active Enrollment for Pivotal Phase III Clinical Trial

STAMFORD, Conn., February 22, 2006 -- Delcath Systems, Inc. (Nasdaq: DCTH), today announced that it has successfully completed a Special Protocol Assessment and Agreement (SPA) with the U.S. Food and Drug Administration (FDA) for the treatment of metastatic melanoma in the liver using the Delcath system with melphalan, an approved anticancer agent.

On February 21st, Delcath received a letter signed by the Acting Director of the Division of Drug Oncology Products of the FDA stating, "We have completed our review of your submissions and have determined that your responses are acceptable..." As a result, active patient enrollment for Delcath's pivotal Phase III clinical trial at the National Cancer Institute (NCI) is expected to begin immediately.

Under the terms of the SPA, the company is required to complete one Phase III trial in order to file a Premarket Approval (PMA) application. The randomized, multi-center trial will enroll 92 patients diagnosed with ocular and cutaneous melanoma metastatic to the liver. Patients who are selected to participate in the trial will be randomized to either the Delcath system using melphalan or a control group receiving best alternative care. Patients in the control group will be reviewed on a case-by-case basis and receive an existing treatment option deemed most appropriate by the principal investigator.

The primary endpoint is to determine whether patients using the Delcath system will experience a reduction in tumor burden or zero progression of the metastatic melanoma in their liver longer than those receiving best alternative care. Participants randomized to the control group whose tumors are found to progress will be allowed to cross over and receive treatment using the Delcath system. Results from the point of crossover will not impact the study.

M.S. Koly, president and chief executive officer of Delcath, stated, "The receipt of SPA approval is a critical step in the advancement of our clinical program. Combined with the recent approval by the NCI's Internal Review Board of the same protocol, the SPA enables our company to move forward with our Phase III study without any further delay and streamlines the FDA approval process. This is an exciting time for the company, the NCI and its patients."

Dr. James F. Pingpank, Jr., principal investigator for Delcath's clinical trials at the NCI, said, "The FDA's final approval for the pivotal Phase III clinical trial protocol serves as an important milestone. Due to the positive results from the Phase I study conducted at the NCI, and building on results achieved with melphalan via a surgical approach, we have received a number of referrals of qualified patients nationwide to participate in the upcoming Phase III trial. Our plan is to begin the active enrollment of patients into this study effective immediately."

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 for specific body

organs or regions.

Special Protocol Assessment

A Special Protocol Assessment (SPA) from the FDA is an agreement that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval. An SPA is binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing is begun. For more information please visit the FDA website: www.fda.gov/CbER/gdlns/protocol.pdf.

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.

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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