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): March 1, 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.)

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))

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Section 8 - Other Events

Item 8.01 Other Events.

On March 1, 2006, Delcath Systems, Inc. (the "Company") issued a press release announcing that the first patient has been treated in the Company's Phase III clinical trial for the treatment of metastatic melanoma in the liver. The Company's press release dated March 1, 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 March 1, 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: March 1, 2006

EXHIBIT INDEX

Exhibit Description

99 Press Release dated March 1, 2006 of Delcath Systems, Inc.

FOR IMMEDIATE RELEASE

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Delcath Systems Announces Initial Patient Treatment In
Phase III Clinical Trial

STAMFORD, Conn., March 1, 2006 -- Delcath Systems, Inc. (NASDAQ: DCTH), today announced that the first patient has been treated with the Delcath System in its pivotal Phase III clinical trial for the treatment of metastatic melanoma in the liver using the Delcath system with melphalan, an approved anticancer agent at the National Cancer Institute (NCI).

The NCI is the first site to enroll patients in the Phase III trial with melphalan. As of February 28, two patients were enrolled and started on therapy. In accordance with the company's Special Protocol Assessment and Agreement (SPA) with the U.S. Food and Drug Administration (FDA), announced February 22, 2006, the multi-center trial requires the enrollment of 92 total patients to determine whether patients using the Delcath system experience a reduction in tumor burden or zero progression of the tumor for a longer period of time than those receiving best alternative care. Patients randomized to the control group whose tumors progress will be allowed to cross over and receive treatment using the Delcath system without impacting the study.

"We believe the trial's positive start can be attributed to the establishment of a protocol the investigators wanted," said M.S. Koly, president and chief executive officer of Delcath. "While the trial needs to be randomized to provide a statistically valid result, the FDA has agreed to allow control arm patients to receive the best alternative care. This removes one of the primary objections of potential investigators to our previous trial, where the use of a specific systemic therapy may not be the best for the patient randomized to the control arm."

"A more important attribute of the randomized trial is the FDA's agreement to accept progression free survival as the primary endpoint. Progression free survival is the length of time a patient is both alive and free from any significant increase in the tumor (free from progression). Control patients whose tumors grow will have completed their portion of the trial and at the principal

investigator's judgment will then be permitted to receive the Delcath treatment. The investigators feel the availability of crossover will greatly speed patient accrual in this study," explains Mr. Koly.

"Delcath's goal all along has been to bring our system to market as quickly and safely as possible. We are convinced that the Delcath system is among the best methods to help many liver cancer patients achieve a significantly better quality of life while dealing with their disease. The SPA agreement with the FDA has allowed us to aggressively proceed down the fast track path and we believe that the enrollment of patients will move quickly, and that the results will convince the FDA of the efficacy of our product," said Mr. Koly. "In addition to the NCI, we are lining up other top cancer centers to join our trial and accelerate patient accrual as we leverage our strong relationships within the medical community, including Dr. Richard Alexander, the recently appointed Associate Chairman of Clinical Research at the University of Maryland School of Medicine in Baltimore."

"While we are excited about commencing the trial, we must follow the NCI's clinical trial guidelines and will not be able to release material information regarding the Phase III trial while it is underway unless investigators publish or present their experiences," Koly concluded.

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.

About Special Protocol Assessment and Agreement (SPA)

An SPA is a written agreement from the FDA that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval, and can only be granted prior to initiation of the clinical trial. An SPA is binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after testing has begun.

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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