## 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): September 30, 2004

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 (Address of principal executive offices)

06905 (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 September 30, 2004, Delcath Systems, Inc. (the "Company") issued a press release relating to the commencement at the National Cancer Institute of a Phase II clinical trial using the Company's technology to deliver high dosages of melphalan for patients with inoperable cancers in the liver. The Company's press release dated September 30, 2004 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

99 Press Release dated September 30, 2004 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

President and Chief Executive Officer

Date: September 30, 2004

# EXHIBIT INDEX

Exhibit Description

99 Press Release dated September 30, 2004 of Delcath Systems, Inc.

Contact:

M.S. Koly Chief Executive Officer Delcath Systems, Inc. 203/323-8668 www.delcath.com Thomas Redington Redington, Inc. 203/222-7399 212/926-1733 www.redingtoninc.com

#### NCI OPENS SECOND CANCER TRIAL WITH DELCATH TECHNOLOGY

Phase II Study Is Testing Delcath-Melphalan Therapy Against Three Types Of Liver Cancers

STAMFORD, CT SEPT. 30 - Delcath Systems, Inc. (Nasdaq: DCTH) said the National Cancer Institute has started treating patients in a Phase II clinical trial using the company's technology to deliver high doses of melphalan for patients with inoperable cancers in the liver.

This is the NCI's second human study of the company's novel delivery system with melphalan. The first patient has been enrolled and successfully treated this past week, the company reported, and NCI researchers are scheduling additional patients for treatment in the coming weeks.

The Delcath technology was originally developed by physicians at the Yale University School of Medicine as rescue therapy for patients with inoperable cancers lodged in specific organs such as the liver, the current focus. No effective treatments are available for the vast majority of cancers once they reach the liver, and patients diagnosed with liver cancers generally survive only nine months on average.

Based on the findings of its first study, the NCI decided to test Delcath-melphalan therapy in three types of inoperable liver tumors: primary liver cancers, neuro-endocrine tumors and adenoid carcinomas that have spread to the liver.

The NCI's earlier work, a Phase I dose-finding study, demonstrated positive results among patients with a broad variety of liver cancers. Sixty percent of the evaluable cancer patients experienced anti-tumor activity, according to NCI researchers, with over half the responding patients achieving tumor shrinkage of greater than 50 percent.

Positive results from the new trial could potentially accelerate use of Delcath's patented technology for a broader range of cancers than was originally anticipated at this stage.

In the new study, up to 25 patients will be enrolled in each of the three disease groups, and each will receive up to four melphalan treatments with the Delcath system. The dosing will be the same as the optimal dose determined in the NCI's Phase I trial for melphalan using

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the drug delivery system, a dose level six times higher than under conventional methods.

There is no control group. The end points are tumor response and the duration of tumor response.

The Delcath system uses special catheters and filters to direct and trap toxic anticancer chemicals so they can be delivered in high doses to body regions or organs while protecting the rest of the body from excessive toxicity.

"The NCI Phase II multi-cancer protocol is a watershed in moving our technology forward toward a broader base of utility at an earlier time than we had originally planned," said M.S. Koly, chief executive officer of Delcath. "Principal Investigator Richard Alexander, MD and his team of oncologists at the NCI continue to communicate strong faith in our technology, and they are doing an excellent job in expanding clinical knowledge of its versatility against different cancers." NCI researchers are also drafting another protocol using the Delcath system.

region-specific delivery of therapeutic agents. Six US and three foreign issued patents cover its technology. The company is headquartered in Stamford, CT.

The company's most advanced study, a multi-center Phase III registration trial using the anticancer drug doxorubicin, is treating patients with inoperable melanoma in the liver.

# # #

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

9/30/04