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 11, 2004

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 and zip code)

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

N/A
(Former name or former address, if changes since last report)



Item 5. Other Events and Regulation FD Disclosure

On March 11, 2004, Delcath Systems, Inc. (the "Company") issued a press release relating to the enrollment of the first patient in its Phase III clinical trial for inoperable cancer in the liver Company's press release dated March 11, 2004 is incorporated herein by reference and filed as an exhibit hereto.

Item 7. Financial Statements and Exhibits.

(a) Not applicable

(b) Not applicable.

(c) Exhibits:

| Exhibit | Description |
|---|---|
| 99 | Press Release dated March 11, 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
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M. S. Koly
President and Chief Executive Officer

Date: March 11, 2004

EXHIBIT INDEX

| Exhibit | Description |
| --- | --- |
| 99 | Press Release dated March 11, 2004 of Delcath Systems, Inc. |

Release Date: IMMEDIATE

Contact:


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


# DELCATH CANCER TREATMENT GIVEN TO FIRST PHASE III PATIENT

## Delcath Plans To Accelerate Enrollment By Opening Two Additional Sites In The US

STAMFORD, CT MAR. 11 - Delcath Systems, Inc. (Nasdaq: DCTH) said clinicians at the Sydney Melanoma Unit in Australia successfully completed the first Delcath treatment in the company's Phase III clinical trial for inoperable cancer in the liver.

The treatment was performed on the study's second enrollee; the first enrollee, announced two days ago, was randomized and assigned to the study's control group, which is treated with a conventional systemic therapy.

Dr. Morton Glickman, who is one of the founders of the company, attended this first procedure at the invitation of Principal Investigator Professor John Thompson. Dr. Glickman has also attended recent Delcath procedures at the National Cancer Institute for the company, and was sent to Australia by Delcath to help train the Sydney clinical team. Following the procedure, Dr. Glickman called the company to report that it was successful. "Professor Thompson is excellent," Dr. Glickman reported, "And the team works well together." Dr. Glickman, an interventional radiologist, is a retired Dean at Yale Medical School and former Chairman of the Department of Radiology and regularly consults to the company on medical issues.

Delcath said it is currently in active discussion with two US cancer centers to become additional sites for the Phase III trial.

"Opening additional sites should not only accelerate enrollment, but also facilitate more timely completion of the Phase III study," notes M.S. Koly, Delcath's CEO. "It is also a positive benefit in gaining clinical exposure for our technology among leading cancer physicians."

In the meantime, the company and the National Cancer Institute (NCI) are working on finalizing a protocol for a Phase II trial at the NCI with melphalan.

On a broader note, Mr. Koly said "Delcath is moving into a period during which significant new accomplishments can be realized, including the expansion of Phase III activities, the start of new studies by Dr.

-more-

Richard Alexander at the NCI with melphalan, and the possibility of testing the Delcath system with front line drugs against colorectal cancer that has spread to the liver, as suggested by experts at our clinical review meeting last month."

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

The study is designed to support FDA approval of Delcath's isolated liver perfusion system which permits delivery of high dose chemotherapy directly to the liver combined with removal of the chemotherapy from the blood before it enters systemic circulation. The FDA-approved protocol calls for enrolling 122 patients (including 61 controls). The Phase III study is testing the drug doxorubicin, against a control group receiving systemic dacarbazine, in patients whose melanoma has spread to the liver. The purpose of the study is to determine whether there is significantly longer survival of patients on the Delcath arm vs. the control group.

The Sydney trial site is being managed on behalf of Delcath by Omnicare,

Inc. (NYSE: OCR), a global contract research organization with 29 principal offices and a presence in 27 countries.

The study's principal investigator John Thompson, MD, Director of the Sydney Melanoma Unit at the Royal Prince Alfred Hospital and professor of surgery (melanoma and surgical oncology) at the University of Sydney, is a world leader in the development of perfusion and infusion therapies for regional treatment of recurrent melanoma.

The Sydney Melanoma Unit has treated more than 15,000 melanoma patients since its inception in 1968, and sees approximately 750 new melanoma patients yearly.

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

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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.