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): January 26, 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 January 26, 2004, Delicate Systems, Inc. (the "Company") issued a press release announcing an update on the experience of the National Cancer Institute using the Company's system for isolated liver perfusion. The Company's press release dated January 26, 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 January 26, 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

M. S. Koly
President and Chief Executive Officer

Date: January 26, 2004

EXHIBIT INDEX

| Exhibit | Description |
| --- | --- |
| 99 | Press Release dated January 26, 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 |


# NCI STUDY WITH DELCATH CANCER TECHNOLOGY REPORTS SIGNIFICANT ANTI-TUMOR ACTIVITY

## 60 Percent of Evaluable Patients Responded To High Dose Therapy Aimed Directly At Tumor

SAN FRANCISCO, CA. JAN 26 - Delcath Systems, Inc. (Nasdaq: DCTH/DCTHW/DCTHZ) said researchers from the National Cancer Institute (NCI) reported an update on their experience using the Delcath system for isolated liver perfusion at the 2004 Gastrointestinal Cancer Symposium held here Jan. 22-24

Dr. James Pingpank, a Senior Investigator of the NCI Surgical Metabolism Section and a colleague of the Section's head, Dr. H. Richard Alexander, told the physicians present that 60 percent of the evaluable cancer patients treated with high dose therapy through the Delcath system experienced anti-tumor activity, with over half of the responding patients achieving tumor shrinkage greater than 50 percent.

Subjects in the study included patients with inoperable primary and metastatic liver cancers of varying origin.

Of particular importance, the NCI reported that the response rate in patients with primary ocular melanoma was higher, with anti-tumor activity observed in 80 percent of evaluable patients.

The NCI study was conducted to determine the optimal dose of the widely prescribed cancer drug melphalan using Delcath's novel technology, an advanced form of site-directed drug delivery. It is designed to allow aggressive chemotherapy by limiting the serious side effects that typically restrict dosing of toxic cancer chemicals.

Researchers said the findings defined 3.0 mg/kg of melphalan as the optimal dose to be tested for anti-tumor effect in future protocols. The dose is at least six times higher than the drug's label recommendation of under 0.5 mg/kg. This represents a much more aggressive use of melphalan than was originally thought possible. Patients in the study were treated with doses as high at 3.5 mg/kg, a dose that could never be delivered by conventional methods.

NCI has finished recruiting patients for the Phase I study since the study goals have been met, but continues to treat and follow enrolled patients for tumor response.

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The company said the NCI's results follow and in some cases improve the tumor response trends experienced in earlier Phase I/Phase II studies using a different drug at MD Anderson and also Yale Medical School where the Delcath technology was first tested. Company officials point out that one of the strengths of the Delcath system is its ability to deliver a wide range of anti-cancer agents. The observation of effects with multiple drug candidates is an important proof of the system's flexibility with a variety of therapeutic regimens.

Data from the study, along with data from other NCI studies, has provided the basis for selecting tumor types to be tested in Phase II trials with the Delcath system now being planned at multiple centers including the NCI. The studies will include patients with several tumor types including metastatic colorectal cancer to the liver. Colorectal cancer, the third most common cancer in men and women in the U.S., has a high tendency to metastasize to the liver where it is very difficult to treat. This pervasive disease is responsible for

over 57,000 deaths a year.

The Delcath system delivers high-dose chemotherapy directly to an organ or body region. In the NCI study, melphalan was delivered to the liver via the hepatic artery. As blood exits the liver, special Delcath filters trap the therapeutic agent, decreasing exposure to the rest of the body and reducing toxicity. The procedure is repeatable and less invasive than traditional ways of performing isolated perfusion to specific body organs or regions.

The 2004 Gastrointestinal Cancer Symposium (San Francisco) was sponsored by the American Society of Clinical Oncology (ASCO), American Gastroenterological Association, American Society for Therapeutic Radiology & Oncology, and the Society of Surgical Oncology.

The NCI presentation is titled "A Phase I Dose-Escalation Study of Hepatic Arterial Melphalan Infusion with Hepatic Venous Hemofiltration Using Percutaneously Placed Catheters in Patients with Unresectable Hepatic Malignancies." This report to the scientific community provided an update to a presentation at the June 2003 ASCO meeting by the study's principal investigator, Dr. H. Richard Alexander, head of the NCI's Surgical Metabolism Section.

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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1/26/04