SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities and Exchange Act of 1934

Date of report (Date of earliest event reported): June 12, 2001

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

001-16133	06-1245881
(Commission File No.)	(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

Item 5. OTHER EVENTS

On June 12, 2001, Delcath Systems, Inc. announced that The National Cancer Institute ("NCI") approved a clinical study protocol for administering escalating doses of melphalan through the Delcath drug delivery system to patients with unresectable cancer of the liver.

The protocol's approval, relayed verbally by the NCI attorney and announced here today at the Company's annual meeting, sets the stage for an NCI-sponsored study to determine the maximally tolerated dose of melphalan administered via isolated perfusion through the Delcath system. The study will also help establish protocols of an anticipated Phase III trial with melphalan.

In earlier work unrelated to Delcath, NCI researchers reported significant tumor reduction and prolonged survival among patients with cancer of the liver who had undergone isolated perfusion therapy with melphalan alone or in combination with other antitumor agents.

The Delcath system, a relatively new advance in perfusion technology, is said to be far less invasive than techniques used earlier by NCI surgeons. More importantly, the Delcath treatment is repeatable, so patients who respond to the therapy can continue to receive treatments to keep their tumors in check. The patented system allows high doses of a drug to be infused directly into the liver along with the organ's normal blood supply. The procedure is non-surgical and does not interrupt the natural circulation of blood within the patient.

The NCI's most recent studies with isolated liver perfusion techniques have involved a lengthy (6-7 hour) surgical procedure in which the right and left lobes of the liver are severed from their diaphragmatic attachments and various tubes and clamps are installed as part of a complex procedure to achieve complete vascular isolation of the organ, thus limiting systemic absorption of the anticancer drug. The mean hospital stay for this surgery is reported to be 11 days.

By contrast, the Delcath system is designed to achieve vascular isolation of the organ in an outpatient setting with a minimally invasive, non-surgical procedure. The system removes the majority of the drug from the blood through a sophisticated catheterization and filtration process.

At the request of the NCI, Delcath demonstrated that its system removes 99.9 percent of melphalan from blood in a laboratory setting.

"The NCI protocol put us on a course to make melphalan the second drug for advanced study with the Delcath system," said M.S. Koly, Delcath's chief executive officer. "We have completed Phase I/II tests with high doses of doxorubicin in patients with cancer of the liver and we will commence a Phase III pivotal trial with the drug later this year."

Up to 27 patients with unresectable malignancies in the liver will be treated under the NCI's dose-escalating protocol. A group of three patients will be treated at 60 mg/square meter of melphalan, the lowest study dose, and up to four additional groups of three patients could each receive 90, 110, 130 and 150 mg/square meter until clinicians observe unallowable toxicity and thereby establish the maximum safe tolerated dose.

The NCI's Surgical Metabolism Section has been studying a role for isolated perfusion in the treatment of patients with cancer of the liver for approximately eight years and believes the Delcath system may potentially expand the number of patients eligible for perfusion therapy with high dose melphalan.

H. Richard Alexander, MD of the NCI's Surgery Branch, notes "many patients with unresectable liver malignancies are not ideal candidates for isolated perfusion with conventional surgical methods. Some patients are ruled-out because the size or location of the tumor makes mobilization and cannulation of the liver impossible. Others have co-existent medical conditions that make the surgery an unacceptable risk. Still others who might benefit from a second procedure are no longer treatable with surgical perfusion due to the extensive scar tissue that develops around the liver after the initial procedure."

Dr. Alexander added, "Our hope is that the Delcath system will provide a far less invasive way to administer high dose melphalan perfusion therapy, expanding the treatment options for patients with inoperable, life-limiting cancer of the liver."

According to Delcath estimates, approximately 222,000 Americans each year are diagnosed with cancer of the liver. Roughly seven percent have primary liver cancer; the balance develop the condition as a result of cancer metastasizing, or spreading, from another point source, such as melanoma, breast, prostate or colorectal cancers.

Delcath is especially excited about the potential for this new melphalan treatment to provide a new treatment alternative for patients with metastases from colorectal disease. NCI researchers have reported that of the 140,000 new patients diagnosed with colorectal cancer in the US annually, 20-30 percent will die of progressive metastatic disease confined to the liver, usually within 12-24 months of diagnosis.

Delcath Systems is the leading developer of isolated perfusion technology for organ or region-specific delivery of therapeutic agents. Its technology is covered by seven US and three foreign issued patents. The Company is headquartered in Stamford, CT.

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.

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.

Dated: June 12, 2001 By: /s/ M.S. Koly

M.S. Koly
President and Chief Executive Officer