

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 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) April 2, 2007 (March 29, 2007)

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

DELAWARE

001-16133

06-1245881

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(State or other jurisdiction  
of incorporation)

(Commission  
File Number)

(IRS Employer  
Identification No.)

1100 SUMMER STREET, STAMFORD, CONNECTICUT

06905

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(Address of principal executive offices)

(Zip Code)

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

N/A

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(Former name or former address, if changed 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))

ITEM 1.01. ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On March 29, 2007, Delcath Systems, Inc. (the "Company") announced that it entered into a five-year extension of its Cooperative Research and Development Agreement (the "CRADA") with the National Cancer Institute ("NCI"), which enhances and expands the initial agreement between the Company and NCI that expired in December 2006. Under the revised CRADA, the Company and NCI agreed that the parties will collaborate in the joint development and evaluation of the Delcath System device to deliver high-dose Melphalan to patients and to evaluate the advisability of developing additional commercial agents for use with the Delcath System, the Company's percutaneous perfusion technology for region-specific delivery of chemotherapeutic and other therapeutic agents.

The revised CRADA also established that NCI's Surgery Branch will work towards completion of Delcath System's ongoing Phase III trial and will serve as the coordinating center when this study expands to a multi-center trial. The Phase III trial is treating patients with melanoma (ocular or cutaneous) metastatic to the liver using the Delcath System and the drug Melphalan.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(a) FINANCIAL STATEMENTS OF BUSINESSES ACQUIRED.

Not applicable.

(b) PRO FORMA FINANCIAL INFORMATION.

Not applicable.

(c) SHELL COMPANY TRANSACTIONS.

Not applicable.

(d) EXHIBITS:

EXHIBIT NO.	DESCRIPTION
99.1	Press Release dated March 29, 2007

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.  
(Registrant)

Date: April 2, 2007

By: /s/ Richard Taney

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Richard Taney, CEO

DELGATH SYSTEMS EXTENDS COOPERATIVE RESEARCH AND DEVELOPMENT  
AGREEMENT WITH THE NATIONAL CANCER INSTITUTE

5-YEAR AGREEMENT PROVIDES FOR EXPANDED DEVELOPMENT OF DELGATH'S REGIONAL  
CANCER THERAPY

STAMFORD, CT, MARCH 29, 2007-Delcath Systems, Inc. (Nasdaq: DCTH) today announced that the Company has signed a five year extension to its Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI"). This extension enhances and expands the initial CRADA that expired in December 2006. The new five year extension provides for the Company and the NCI to collaborate in the joint development and evaluation of the Delcath Systems device to deliver high-dose Melphalan to patients, and to evaluate the advisability of developing additional commercial agents for use with the Delcath System, the Company's percutaneous perfusion technology for region-specific delivery of chemotherapeutic and other therapeutic agents.

Under the new agreement, the Surgery Branch of the NCI will work towards completion of Delcath System's pivotal ongoing Phase III trial for patients with metastatic melanoma in the liver using the drug Melphalan, and is expected to serve as the coordinating center when this study expands to a multi-center trial. The Phase III study is treating patients with ocular and cutaneous melanoma who have unresectable tumors in the liver, using the Delcath System to deliver the drug. The Delcath System is designed to isolate the patient's liver in order to allow significantly higher dosing of Melphalan while limiting the systemic toxicities that result from current intravenous chemotherapy treatments.

Patients in the Phase III trial are randomly assigned to one of two initial treatment arms, for immediate treatment with Melphalan via the Delcath System, or alternatively, treatment with best alternative care. The study is designed to evaluate the duration of tumor response in each of the two arms of the study. Following the guidelines established by the FDA for this trial under a Special Protocol Assessment, when the disease progresses (tumor grows) in patients receiving best alternative care, they are allowed to "cross over" and receive treatment with the Delcath System. The FDA has approved expansion of the trial to include up to 15 centers. Upon appropriate NCI Institutional Review Board ("IRB") approval (currently pending), this trial will be expanded to a multi-center trial.

The NCI will continue conducting the Phase II clinical study of Melphalan in patients with primary and metastatic hepatic malignancies using the Delcath System. One of the arms of this multi-histology study was recently expanded to include twenty-five patients after showing tumor response in 75% of the patients treated to date. These results generated significant interest among cancer researchers when they were presented at a recent international cancer symposium this past February. The NCI will also conduct pharmacokinetic analyses of patient samples in the Phase II and Phase III clinical trials to characterize the pharmacokinetic advantage of Melphalan delivered to the liver using the Delcath System, will provide and perform primary database management and statistical analysis for the Melphalan trials, and will conduct ongoing hematological biocompatibility and extraction testing of Melphalan in human plasma and whole blood.

In addition, the NCI may perform preclinical animal and filter testing to provide the basis for supporting Phase I trials for additional chemotherapeutics. Investigating different chemotherapeutics such as Oxaliplatin, along with development of additional protocols utilizing the Delcath System for the isolated treatment of cancers in other body regions (such as colorectal, limb and pancreatic), may be conducted by mutual agreement of Delcath and the NCI.

Richard L. Taney, Chief Executive Officer of Delcath Systems, commented on the agreement, "We are very pleased to have reached an expanded CRADA with the NCI. This is a significant milestone for Delcath as it allows us to continue our collaboration with the world's premier oncology researchers and clinicians in order to advance the clinical development of the Delcath System, thereby bringing regional cancer therapy to patients with limited treatment options. Importantly, it provides for the expected expansion of the current Phase III trial into a multi-center trial, which should accelerate patient recruitment and propel the Delcath System toward commercialization."

"The breadth of this five-year agreement underscores the potential for our organ or region-specific delivery of therapeutic agents to better treat cancer patients. This enhanced collaboration allows for the potential expansion of our platform perfusion technology to other approved chemotherapeutics via the Delcath System, a goal which remains a primary strategic objective of our company" concluded Mr. Taney.

## ABOUT THE NATIONAL CANCER INSTITUTE

The National Cancer Institute, established under the National Cancer Institute Act of 1937, is the Federal Government's principal agency for cancer research and training. The National Cancer Institute coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients

## ABOUT DELCATH SYSTEMS, INC.

Delcath Systems is a developer of percutaneous perfusion technology for organ or region-specific delivery of therapeutic and chemotherapeutic 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](http://WWW.DELCATH.COM).

THIS RELEASE CONTAINS FORWARD-LOOKING STATEMENTS, WHICH ARE SUBJECT TO CERTAIN RISKS AND UNCERTAINTIES THAT CAN CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE DESCRIBED. FACTORS THAT MAY CAUSE SUCH DIFFERENCES INCLUDE, BUT ARE NOT LIMITED TO, UNCERTAINTIES RELATING TO OUR ABILITY TO SUCCESSFULLY COMPLETE PHASE III CLINICAL TRIALS AND SECURE REGULATORY APPROVAL OF OUR CURRENT OR FUTURE DRUG-DELIVERY SYSTEM AND UNCERTAINTIES REGARDING OUR ABILITY TO OBTAIN FINANCIAL AND OTHER RESOURCES FOR ANY RESEARCH, DEVELOPMENT AND COMMERCIALIZATION ACTIVITIES. THESE FACTORS, AND OTHERS, ARE DISCUSSED FROM TIME TO TIME IN OUR FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION. YOU SHOULD NOT PLACE UNDUE RELIANCE ON THESE FORWARD-LOOKING STATEMENTS, WHICH SPEAK ONLY AS OF THE DATE THEY ARE MADE. WE UNDERTAKE NO OBLIGATION TO PUBLICLY UPDATE OR REVISE THESE FORWARD-LOOKING STATEMENTS TO REFLECT EVENTS OR CIRCUMSTANCES AFTER THE DATE THEY ARE MADE.