

**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

November 20, 2007 (November 20, 2007)

Date of Report (Date of earliest event reported)

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-16133

(Commission File No.)

06-1245881

(IRS Employer
Identification No.)

**600 Fifth Avenue, 23rd Floor
New York, NY 10020**

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(212) 489-2100**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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 8.01 OTHER EVENTS.

On November 20, 2007, Delcath Systems, Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has notified the Company that patient enrollment may resume in the Phase III and Phase II clinical trials of the Delcath System. Current and prospective clinical investigation sites have been notified that study accrual can be resumed immediately. This decision follows the Company's meeting with representatives of the FDA, along with the Principal Investigator at the National Cancer Institute ("NCI").

The Company's resumption of study accrual follows a voluntary enrollment deferral announced by the Company on October 23, 2007 in response to an FDA inquiry into certain gastrointestinal adverse events observed in four patients enrolled in the studies of the Delcath System prior to protocol changes enacted earlier this year. During the meeting at the FDA, which was attended by senior reviewers from both the Drug and Device arms of the Agency, the Principal Investigator presented an analysis of the previously reported gastrointestinal toxicities and of the changes incorporated into the trial protocols to prevent a recurrence of (GI) toxicities. These changes had been previously approved by the NCI Institutional Review Board and were subsequently approved by the Data Safety Monitoring Board for the Phase III trial. The Company has been notified in writing by the FDA that the studies can proceed with the amended protocol.

A copy of the Company's press release announcing the events described above is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

- (a) Not applicable.
- (b) Not applicable.
- (c) Not applicable.
- (d) Exhibits

No.	Description
<u>99.1</u>	Press release of the Company dated November 20, 2007

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 20, 2007

DELCATH SYSTEMS, INC.

By: /s/ Richard L. Taney

Name: Richard L. Taney

Title: Chief Executive Officer

EXHIBIT INDEX

No.	Description
99.1	Press release of the Company dated November 20, 2007

Company Contact:

Delcath Systems, Inc.

Richard Taney

(212) 489-2100

www.delcath.com

Investor Relations Contacts:

Lippert/Heilshorn & Associates, Inc.

Anne Marie Fields

afields@lhai.com

(212) 838-3777

Bruce Voss (bvoss@lhai.com)

(310) 691-7100

www.lhai.com

DEL CATH RESUMES ENROLLMENT IN PHASE III AND PHASE II TRIALS

NEW YORK (November 20, 2007) - Delcath Systems, Inc. (NASDAQ:DCTH) announces that the U.S. Food and Drug Administration (FDA) has notified the Company that patient enrollment may resume in the Phase III and Phase II clinical trials of the Delcath System. Current and prospective clinical investigation sites have been notified that study accrual can be resumed immediately. This decision follows Delcath's meeting with representatives of the U.S. Food and Drug Administration (FDA), along with the Principal Investigator at the National Cancer Institute (NCI).

Resumption of study accrual follows a voluntary enrollment deferral announced by the Company on October 23, 2007 in response to an FDA inquiry into certain gastrointestinal adverse events observed in four patients enrolled in the studies of the Delcath System prior to protocol changes enacted earlier this year. During the meeting at the FDA, which was attended by senior reviewers from both the Drug and Device arms of the Agency, the Principal Investigator presented an analysis of the previously reported gastrointestinal toxicities and of the changes incorporated into the trial protocols to prevent a recurrence of (GI) toxicities. These changes had been previously approved by the NCI Institutional Review Board (IRB) and were subsequently approved by the Data Safety Monitoring Board (DSMB) for the Phase III trial. The Company has been notified in writing by the FDA that the studies can proceed with the amended protocol.

"We are pleased with the Agency's prompt response to and resolution of this issue. We are very appreciative of the timely assistance of the NCI which allowed us to respond to the Agency less than a week after receiving the letter and their presentation of the data contributed greatly to the unusually quick resolution of this matter. A thorough analysis of the clinical facts surrounding these episodes combined with the clinical benefits demonstrated by the Delcath System for these extremely ill patients allowed for a balanced evaluation of FDA safety concerns," said Richard L. Taney, President and Chief Executive Officer of Delcath Systems.

"We look forward to recruiting additional oncology centers for the expansion of our clinical trials as we believe that use of the Delcath System for the targeted, region-specific delivery of high

dose chemotherapeutic agents can bring significant clinical benefit to late-stage cancer patients with very limited treatment options, and consequently, poor prognoses, " concluded Mr. Taney.

The Phase III Trial

The Phase III study, now resuming enrollment at the NCI, is testing the Delcath System for the regional delivery of melphalan to the liver to treat patients with metastatic ocular and cutaneous melanoma who have unresectable tumors in the liver. The Delcath System isolates the blood flow within the patient's liver in order to allow significantly higher doses of the anti-cancer drug to be administered while limiting the toxicities that result from current systemic chemotherapy treatments.

Patients in the Phase III trial initially are randomized into one of two treatment arms, including immediate treatment with melphalan via the Delcath System or treatment with best alternative care. The study is designed to evaluate the duration of tumor response in each of the two study arms. Following guidelines established by FDA under a Special Protocol Assessment, when disease progresses in patients enrolled in the best alternative care arm of the trial, they are permitted to "cross over" and receive treatment with the Delcath System.

The Phase II Trial

The Phase II clinical trial, also resuming enrollment at the NCI, is testing use of the Delcath System for the organ-specific delivery of the chemotherapeutic agent melphalan in patients with specific tumors in the liver, including primary liver cancer, metastatic neuroendocrine tumors, adenocarcinomas in the liver, and metastatic melanoma in the liver of patients who previously received isolated hepatic perfusion, but whose cancer has since returned.

About Delcath Systems, Inc.

Delcath Systems is a developmental stage company testing its percutaneous perfusion technology for the isolated organ and region specific delivery of therapeutic and chemotherapeutic agents. The Delcath System is currently being tested with the drug Melphalan in a Phase III trial of patients with metastatic ocular and cutaneous melanoma in the liver, and a Phase II trial of patients with primary liver cancers and metastatic tumors in the liver from neuroendocrine cancers, adenocarcinomas, as well as patients with melanoma who previously received isolated perfusion. The Company's intellectual property portfolio currently consists of eighteen patents on a worldwide basis including the U.S., Europe, Asia and Canada. For more information, please visit the Company's website at www.delcath.com.

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news 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.

###
