DELCATH SYSTEMS INC
Form 8-K
November 20, 2007

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	**001-16133**	**06-1245881**
(State or other jurisdiction of incorporation)	(Commission File No.)	(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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**
99.1	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