DELCATH SYSTEMS INC
Form 8-K
October 26, 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

October 26, 2007 (October 22, 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 October 22, 2007, Delcath Systems, Inc. (the Company) received a letter from the U.S. Food and Drug Administration (the FDA) recommending that the Company temporarily suspend enrollment in the Phase III and Phase II trials of the Delcath System, and submit an analysis of adverse events in anticipation of a meeting with the FDA to discuss certain gastrointestinal (GI) safety concerns.

The recommendation was issued by the FDA following reports of four serious adverse GI events that the Company submitted to the FDA, the National Cancer Institute, the Institutional Review Board and the Data Safety Monitoring Board, that may have been related to the infusion of melphalan. The Company plans to submit to the FDA its analysis of these adverse events and their relation to the Delcath System within fifteen days. The Company also intends to meet with the FDA to address the issues it raised, and to present changes that have already been made to the trial protocols that the Company believes will remedy the FDA s safety concerns. Until such time, the Company has decided to voluntarily defer accrual of new patients in the Phase III and Phase II trials pending a meeting with the FDA. The Company anticipates that patients currently enrolled in the trials will continue to receive their treatments under the approved protocols.

The Company s management hosted an investment conference call at 10:00 a.m. Eastern Time on Tuesday, October 23, 2007 to discuss these developments and to answer questions.

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 October 23, 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: October 26, 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 October 23, 2007