

DELCATH SYSTEMS INC
Form 8-K
April 24, 2009

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 22, 2009

DELCATH SYSTEMS, INC.
(Exact Name of Registrant as
Specified in Charter)

DELAWARE	001-16133	06-1245881
(State of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

600 FIFTH AVENUE, 23rd FLOOR NEW YORK, NEW YORK	10020
(Address of Principal Executive Offices)	(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 obligation of the registrant under any of the following provisions:

- ☐ 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 7.01 Regulation FD Disclosure.

On April 22, 2009, Delcath Systems, Inc. (the “Company”) held a previously noticed quarterly update conference call and access thereto. The call will be archived and made available shortly on the Company’s website, www.delcath.com. On the call, among other things, the Company announced that it was granted FDA approval to increase the maximum number of centers that can participate in the Company’s trials from the current 15 to a maximum of 28 centers. It was also announced that patient enrollment passed the halfway point in December and accrual is set to exceed 75% by this summer. It was further announced that the Company remains on its stated target to complete enrollment in its trials by year-end 2009, with current enrollment currently at 61 patients, of which 31 have been randomized to receive the Delcath treatment and 30 have been randomized to receive best alternative care.

The information contained in Item 7.01 of this Report shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act.

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 report 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 the timing of and our ability to successfully enroll patients or otherwise 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.

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.

Date: April 23, 2009

DELCATH SYSTEMS, INC.

By:	/s/ Richard L. Taney	
Name:		Richard L. Taney
Title:		Chief Executive Officer