

DELCATH SYSTEMS INC
Form 8-K
April 21, 2010

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 21, 2010

DELCATH SYSTEMS, INC.

(Exact Name of Registrant as Specified in Charter)

DELAWARE
(State of Incorporation)

001-16133
(Commission File Number)

06-1245881
(IRS Employer Identification
No.)

600 FIFTH AVENUE, 23RD FLOOR
NEW YORK, NEW YORK
(Address of Principal Executive Offices)

10020
(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 communication 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 April 21, 2010, Delcath Systems, Inc. issued a press release announcing that its Phase III National Cancer Institute (NCI)-led multi-center clinical trial has successfully met the study's primary endpoint of extended hepatic progression-free survival (hPFS) in patients with melanoma metastases to the liver based on an independently corroborated intent-to-treat analysis. Comparing treatment with the Delcath PHP System™ with melphalan to Best Alternative Care (BAC), based on independent core lab review of patient scans, the statistical analysis revealed that the PHP patients had a statistically significant longer median hPFS of 214 days compared to 70 days in the BAC arm (p=0.001). This reflects a 144-day prolongation of hPFS over that of BAC control arm, with less than half the risk of progression and/or death in the PHP group compared to the BAC group (Hazard Ratio = 0.46). A copy of Delcath's April 21, 2010 press release is included in Exhibit 99.1 to this Current Report on Form 8-K.

The Company will host a conference call today to discuss these results at 5:15 p.m. ET. Eamonn Hobbs, CEO, Dave McDonald, CFO, Dr. Kris Kandarpa, CMO, and Jason Rifkin, SVP of Clinical Affairs will host the call. To participate in the live call by telephone, please dial 877-941-8609 for domestic participants and 480-629-9031 for international participants. Participants are asked to call the above numbers 5-10 minutes prior to the starting time. The call will also be webcast live at www.delcath.com. An audio replay of the call will be available for 7 days following the call. This replay can be accessed by dialing 800-406-7325 for domestic callers and 303-590-3030 for international callers, both using passcode 4287086#. An archived webcast will also be available at www.delcath.com.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this report on Form 8-K:

Exhibit Number
99.1

Description of Exhibit
Press Release of Delcath Systems, Inc. dated April 21, 2010

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 21, 2010

DELCATH SYSTEMS, INC.

By: /s/ David A. McDonald
Name: David A. McDonald
Title: Chief Financial Officer
