

DELCATH SYSTEMS INC
Form 8-K
January 13, 2012

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): January 13, 2012 (January 12, 2012)

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

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| Delaware (State or Other Jurisdiction of Incorporation) | 001-16133 (Commission File Number) | 06-1245881 (IRS Employer Identification Number) |
|---|---------------------------------------|---|

810 Seventh Avenue, 35th Floor, New York, New York, 10019
(Address of principal executive offices, including zip code)

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

NONE
(Former name or former address, if changed since last report)

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 (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 January 12, 2012, Delcath Systems, Inc. (the “Company”) met with the United States Food & Drug Administration (FDA) to conduct the scheduled pre-New Drug Application (NDA) meeting. Based upon the meeting and FDA correspondence received in response to our meeting request and the briefing packet we submitted, we are satisfied with the responses that we received from the FDA to certain questions we had regarding the NDA submission. Accordingly, we will continue with the preparation of our NDA submission as planned and expect to make the submission in the second quarter of 2012.

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.

DELCATH SYSTEMS, INC.

Dated: January 13, 2012

By: /s/ Peter J. Graham
Name: Peter J. Graham
Title: Executive Vice President,
General Counsel