

DELCATH SYSTEMS INC  
Form 8-K  
October 28, 2011

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): October 28, 2011 (October 26, 2011)

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

|                                                   |                          |                                         |
|---------------------------------------------------|--------------------------|-----------------------------------------|
| Delaware                                          | 001-16133                | 06-1245881                              |
| (State or Other Jurisdiction<br>of Incorporation) | (Commission File Number) | (IRS Employer<br>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 October 26, 2011, Delcath Systems, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has responded to the Company's request made in September for a pre-New Drug Application (NDA) meeting and has scheduled a date in mid-January 2012. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

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Item 9.01. Financial Statements and Exhibits.

The following exhibits are filed herewith:

(d) Exhibits.

| Exhibit No. | Description |
|-------------|-------------|
|-------------|-------------|

|      |                                                                |
|------|----------------------------------------------------------------|
| 99.1 | Press Release of Delcath Systems, Inc., dated October 26, 2011 |
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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: October 28, 2011

|        |                                              |
|--------|----------------------------------------------|
| By:    | /s/ Peter J. Graham                          |
| Name:  | Peter J. Graham                              |
| Title: | Executive Vice President,<br>General Counsel |

EXHIBIT INDEX

| Exhibit No. | Description                                                    |
|-------------|----------------------------------------------------------------|
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