

DELCATH SYSTEMS INC  
Form 8-K  
November 01, 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): November 1, 2012**

**DELCATH SYSTEMS, INC.**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or Other Jurisdiction**  
  
**of Incorporation)**

**001-16133**  
**(Commission**  
  
**File Number)**

**06-1245881**  
**(IRS Employer**  
  
**Identification Number)**

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810 Seventh Avenue, 35<sup>th</sup> 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 November 1, 2012, Delcath Systems, Inc. (the Company ) issued a press release announcing that the U.S. Food and Drug Administration (the FDA ) assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013, for substantive review of the Company s New Drug Application ( NDA ) for its proprietary chemosaturator system with melphalan hydrochloride for injection. The FDA accepted the Company s NDA submission for filing on October 14, 2012, and designated the NDA for standard review.

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.

**Item 9.01. Financial Statements and Exhibits.**

The following exhibits are filed herewith:

(d) Exhibits.

| <b>Exhibit<br/>No.</b> | <b>Description</b>   |
|------------------------|--|
| 99.1                   | Press Release of Delcath Systems, Inc., dated November 1, 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: November 1, 2012

By: /s/ Peter J. Graham

Name: Peter J. Graham

Title: Executive Vice President, General Counsel

**EXHIBIT INDEX**

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