

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, 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 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 chemosaturation 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.

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