

DELCATH SYSTEMS INC
Form 8-K
December 05, 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): December 5, 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 December 5, 2012, Delcath Systems, Inc. issued a press release announcing that after recent discussions with the U.S. Food & Drug Administration (FDA), management has elected to modify the label indication it is seeking in its New Drug Application (NDA) for its proprietary chemosaturation system with melphalan hydrochloride for injection to focus on the treatment of patients with unresectable metastatic ocular melanoma in the liver. 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 exhibit is filed herewith:

(d) Exhibits.

Exhibit

| No. | Description |
|------------|---|
| 99.1 | Press Release of Delcath Systems, Inc. dated December 5, 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: December 5, 2012

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

General Counsel

EXHIBIT INDEX

Exhibit

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|------------|--|
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