

DELCATH SYSTEMS INC
Form 8-K
February 23, 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): February 22, 2011

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) |
|---|---------------------------------------|---|

810 Seventh Avenue, Suite 3505, 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))
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Item 8.01. Other Events.

On February 22, 2011, Delcath Systems, Inc. issued a press release announcing that it has received a "refusal to file" letter from the U.S. Food & Drug Administration for the New Drug Application for its proprietary chemosaturation system used in the treatment of patients with metastatic melanoma in the liver through the percutaneous intra-arterial administration of melphalan hydrochloride. It also announced the CE Mark Technical File review process for marketing approval of the Hepatic ChemoSAT™ Delivery System continues on schedule and provided certain information on its cash position. 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 February 22, 2011 |

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: February 22, 2011

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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