

DELCATH SYSTEMS INC
Form 8-K
October 19, 2010

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 13, 2010

DELCATH SYSTEMS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-16133	06-1245881
(State of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

810 Seventh Avenue, Suite 3505
New York, New York 10019
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (212) 489-2100

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 communication 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))

Section 1 – Registrant’s Business and Operations

Item 1.01. Entry into a Material Definitive Agreement.

On October 13, 2010, Delcath Systems, Inc. (“Delcath”) entered into a License, Supply and Contract Manufacturing Agreement (the “Agreement”) with Synerx Pharma, LLC (“Synerx”) and Bioniche Teoranta (“Bioniche Pharma”) for the supply of Delcath’s brand of melphalan hydrochloride for injection (“Product”). Pursuant to the Agreement, Synerx granted Delcath a limited right of reference to the Synerx Abbreviated New Drug Application for melphalan hydrochloride for injection (the “Synerx ANDA”), as incorporated into Delcath’s chemosaturation system for percutaneous hepatic perfusion (the “PHP System”), in the United States (the “Territory”), and Bioniche Pharma has agreed to supply Delcath with Product. The approved Synerx ANDA and its associated files are registered to Synerx and licensed to Bioniche Pharma for manufacturing and distribution in the Territory. In accordance with the terms of the Agreement, Delcath was granted a license to reference the Synerx ANDA as part of Delcath’s New Drug Application (“NDA”) to the United States Food and Drug Administration (“FDA”) for the PHP System. Further, during the term of the Agreement, Synerx has agreed that it will not grant a license in the Synerx ANDA to competitors of Delcath for use in the Territory in the field of chemosaturation for percutaneous hepatic perfusion.

The Agreement is effective as of October 13, 2010 and will continue for a period of seven years from the first day of the third month following the date on which Delcath receives notice of FDA approval of its NDA. The Agreement is renewable for successive one year periods upon mutual agreement of the parties. Pursuant to the terms of the Agreement, Delcath paid each of Synerx and Bioniche Pharma \$250,000 upon execution and will pay each of Synerx and Bioniche Pharma \$250,000 within ten days of FDA approval of Delcath’s NDA. Delcath will pay Bioniche Pharma for Product ordered in accordance with the terms and conditions of the Agreement and has agreed to annual minimum Product purchase requirements.

The foregoing description of the Agreement is qualified in its entirety by reference to the Supply Agreement, which Delcath intends to file as an exhibit to its Annual Report on Form 10-K for its fiscal year ending December 31, 2010 and is incorporated by reference herein. Delcath intends to seek confidential treatment of certain terms of the Agreement in connection with the filing of such agreement in accordance with the procedures of the Securities and Exchange Commission.

Section 8 – Other Events

Section 8.01. Other Events.

On October 14, 2010, Delcath Systems, Inc. issued a press release announcing that it had entered into the License, Supply and Contract Manufacturing Agreement with Synerx Pharma, LLC and Bioniche Teoranta. 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.

Section 9 – Financial Statements and Exhibits

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
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99.1 Press release of Delcath Systems, Inc., dated October 14, 2010

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release of Delcath Systems, Inc., dated October 14, 2010.

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.

Date: October 19, 2010

DELCATH SYSTEMS, INC.

By: /s/ Peter J. Graham
Name: Peter J. Graham
Title: Executive Vice President
and General Counsel
