

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
(State of Incorporation)

001-16133
(Commission File Number)

06-1245881
(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))
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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

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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



FOR IMMEDIATE RELEASE

DELCATH SIGNS AGREEMENT WITH SYNERX AND MYLAN'S BIONICHE TEORANTA FOR MELPHALAN SUPPLY

NEW YORK, NY – October 14, 2010 -- Delcath Systems, Inc. (NASDAQ: DCTH) announced today that it has executed a multi-year supply agreement with Synerx Pharma, LLC and Bioniche Teoranta, an affiliate of Mylan, Inc., for the supply of Delcath's branded melphalan hydrochloride for injection ("melphalan"). Melphalan is the chemotherapeutic drug used with Delcath's Chemosaturation system in its Phase III clinical study for the treatment of patients with hepatic metastases from ocular or cutaneous melanoma.

This agreement provides Delcath an exclusive right of reference to the Synerx Abbreviated New Drug Application (ANDA) for use with the Delcath ChemoSaturation system as well as a reliable, long-term and already United States Food and Drug Administration (FDA) approved source of melphalan for the U.S. market. The approved ANDA and its associated files are registered to Synerx and licensed to Bioniche Teoranta. Under the terms of the agreement, Synerx will grant Delcath a limited license to reference the ANDA and associated data files in Delcath's New Drug Application ("NDA") submission, and Bioniche Teoranta shall manufacture and supply Delcath with Delcath-branded melphalan hydrochloride through its FDA-approved cGMP (current Good Manufacturing Practices) contract manufacturer. The term of the agreement is seven years following FDA approval of Delcath's NDA.

"We are extremely pleased to have signed an agreement with such established and market-leading companies as Synerx and Mylan's Bioniche. We believe that the right to reference an approved ANDA for melphalan and utilize a proven supply chain will greatly simplify and enhance the quality of our own NDA submission," said Eamonn P. Hobbs, President and CEO of Delcath Systems. "We are presently preparing the remaining modules for our NDA submission to the FDA, and continue to expect to complete our NDA filing during the fourth quarter of 2010."

About Delcath Systems

Delcath Systems, Inc. is a development stage, specialty pharmaceutical and medical device company focused on oncology. Delcath's proprietary system for chemosaturation is designed to administer high dose chemotherapy and other therapeutic agents to diseased organs or regions of the body, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and metastatic liver

cancers. In 2010, Delcath concluded a Phase III metastatic melanoma study, and the Company recently completed a multi-arm Phase II trial to treat other liver cancers. The Company has not yet received FDA or any foreign regulatory approval for commercial sale of its system. For more information, please visit the Company's website at www.delcath.com.

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to uncertainties relating to the acceptability of the Phase III clinical trial data by the FDA, our ability to successfully complete an FDA New Drug Application (NDA) during the fourth quarter of 2010, benefits to our NDA submission to the FDA from the Synerx/Bioniche agreement, if any, acceptance of the new drug application by the FDA, approval by the FDA or other regulatory authorities of the current or future drug delivery system for the treatment of metastatic melanoma, the future reliability of melphalan supply for the U.S. market, our ability to successfully complete other clinical trials and secure regulatory approval of our current or future drug-delivery system for the treatment of other liver cancers and other organs, the potential of chemosaturation therapy via PHP as a treatment for patients with terminal metastatic disease in the liver, actions by the FDA or other regulatory agencies, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, and uncertainties regarding our ability to obtain financial and other resources for any research, development and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

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