

DELCATH SYSTEMS INC
Form 8-K
February 10, 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): February 4, 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.)

600 FIFTH AVENUE, 23RD FLOOR
NEW YORK, NEW YORK
(Address of Principal Executive Offices)

10020
(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:

- ☐ 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))

Item 1.01. Entry into a Material Definitive Agreement.

Research and Distribution Agreement. Delcath Systems, Inc. ("Delcath" or the "Company") entered into a research and distribution agreement with Chi-Fu Trading Co., Ltd., a corporation organized and existing under the laws of Taiwan, dated February 9, 2010 (the "Research and Distribution Agreement"). The Research and Distribution Agreement grants Chi-Fu the exclusive right to promote, market, sell and distribute the Delcath Percutaneous Hepatic Perfusion System, or the Delcath PHP System,TM in Taiwan for hepatic malignancies and infectious disease upon Taiwan Food and Drug Administration (TFDA) approval, and for any other TFDA approved indications for treatment using the Delcath PHP System (collectively, the "Field of Use"). The agreement also grants Chi-Fu the right to extend its exclusive distribution rights to Singapore, subject to the satisfaction of certain conditions.

Pursuant to the Research and Distribution Agreement Chi-Fu will plan, fund and manage clinical studies of the Delcath PHP System in the Field of Use with initial focus on the treatment of hepatic malignancies at not less than two and up to four sites in Taiwan, and will promptly file for TFDA approval of the Delcath PHP System for as many indications of use as possible, promptly following Delcath's receipt of U.S. Food and Drug Administration (FDA) approval of the Delcath PHP System. Chi-Fu's exclusive right to market, sell and distribute the Delcath PHP System in Taiwan in the Field of Use will begin on the date TFDA approval of the Delcath PHP System is granted and will continue for the term of the agreement. Beginning on the first day of the month in which TFDA approval is obtained, Chi-Fu is obligated to purchase a minimum number of Delcath PHP Systems annually during the term of the agreement; with such minimum purchase requirements to increase annually over the remaining term of the agreement. The Research and Distribution Agreement, requires Chi-Fu to pay Delcath \$1 million (USD) in milestone payments, comprised of \$300,000 (USD) upon execution of the agreement and the balance in two installments, upon receipt of the CE Mark and upon receipt of FDA approval.

The term of the Research and Distribution Agreement commenced on February 9, 2010 and will continue for five (5) years from the first day of the month in which TFDA approval is obtained, following which the agreement will automatically renew for an additional five (5) years provided Chi-Fu has met all of its obligations under the agreement, including its minimum purchase requirements. The Research and Distribution Agreement contains other customary terms and conditions for transactions of this type, including: clinical trial protocol and conduct requirements; cooperation in securing necessary government and other approvals; distributor representations and warranties and obligations and covenants with respect to Chi-Fu's marketing, sale and distribution of the Delcath PHP System; minimum inventory requirements; indemnities and product warranties.

A copy of the press release announcing Delcath's entry into the Research and Distribution Agreement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Lease. On February 5, 2010, Delcath entered into an agreement of lease ("Lease") with SLG 810 Seventh Lessee LLC (the "Landlord") for the lease of approximately 8,629 square feet of office space located at 810 Seventh Avenue, 35th Floor, Suite 3505, New York, New York, with the option to expand an additional 8,629 square feet. Delcath's executive offices will be relocated to this new office space.

The term of the Lease will begin on the earlier of (i) the date on which the Landlord's build-out of the leased premises is substantially completed and (ii) the date on which Delcath first occupies the leased premises (the "Commencement Date") and will continue for seven (7) years and six (6) months, with the option to renew for an additional five (5) year term. The Lease provides for total annual base rental payments of \$457,337, payable in advance in monthly installments of \$38,111.42, during years 1, 2, 3 and the first half of year 4 of the Lease term (which is abated during the first 6 months of the term), and of \$491,853, payable in advance in monthly installments of \$40,987.75, during the second half of year 4 and years 5, 6, and 7 of the Lease term. The Lease also requires Delcath to pay additional rent

for electricity utilized in the leased premises, certain repair costs for items in

the leased premises and the Company's share of the increase in costs above the current year for real estate taxes and operating expenses.

The foregoing descriptions of the Research and Distribution Agreement and the Lease are qualified in their entirety by reference to the full text of the agreements which Delcath intends to file with the Securities and Exchange Commission as exhibits to its quarterly report on Form 10-Q for its first fiscal quarter ending March 31, 2010 and are incorporated by reference herein. Delcath also intends to seek confidential treatment of certain terms of the Research and Distribution Agreement in connection with the filing of such agreements in accordance with the procedures of the Securities and Exchange Commission. Delcath PHP System™ is a trademark of Delcath Systems, Inc. All rights reserved.

Item 8.01 Other Events.

On February 4, 2010, Delcath issued a press release announcing that sufficient events had been reached to allow data analysis to begin of its Phase III clinical trial for the treatment of metastatic melanoma in the liver using the Delcath PHP System. A copy of Delcath's February 4, 2010 press release is included in Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this report on Form 8-K:

Exhibit Number	Description of Exhibit
99.1	Press Release of Delcath Systems, Inc. dated February 9, 2010
99.2	Press Release of Delcath Systems, Inc. dated February 4, 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: February 10, 2010

DELCATH SYSTEMS, INC.

By: /s/ David A. McDonald
Name: David A. McDonald
Title: Chief Financial Officer