

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 21, 2009

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 8.01 Other Events.

On October 21, 2009, Delcath Systems, Inc. (the “Company”) issued a press release announcing that its pivotal Phase III Metastatic Melanoma Trial has met its goal of 92 patients and is fully enrolled.

A copy of the press release, dated October 21, 2009, is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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 October 21, 2009

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 21, 2009

DELCATH SYSTEMS, INC.

By: /s/ Eamonn Hobbs

Name: Eamonn Hobbs

Title: Chief Executive Officer



Delcath Systems, Inc. Completes Phase III Study Enrollment

NEW YORK, NY, October 21, 2009, -- Delcath Systems, Inc. (Nasdaq: DCTH), a medical technology company testing its proprietary treatment method for primary and metastatic cancers to the liver, announced today that its pivotal Phase III Metastatic Melanoma Trial has met its goal of 92 patients and is fully enrolled. This clinical study is evaluating the Delcath PHP System™ for the regional delivery of melphalan to the liver to treat patients with metastatic cutaneous and ocular melanoma who have unresectable tumors in the liver.

With the achievement of complete enrollment, the company remains on-track for a FDA submission of its Delcath PHP System™ with melphalan in 2010. Trial enrollment will continue for the near-term, to include additional patients that have begun the evaluation process and may be eligible to participate.

“We always expected to see the greatest enrollment activity in the second half of the study period as positive word about the Delcath PHP System spread and attracted new patients to the study,” said Eamonn Hobbs, President and CEO of Delcath Systems. “We are delighted to have completed enrollment on-plan, and to continue the extremely positive momentum created over the last six months. We have achieved several key, strategic milestones, including the successful review of our Phase III safety data, orphan drug designation for doxorubicin for the treatment of hepatocellular carcinoma, and the additions of David McDonald as Chief Financial Officer and Dr. Krishna Kandarpa as Chief Medical Officer and EVP of Research and Development. We also executed on our plans to build our own manufacturing facility, which we will continue to develop as we focus for the remainder of the year on preparation for our FDA submission, commercialization and international licensing.”

About the Phase III Study

This clinical study is testing the Delcath PHP System™ for the regional delivery of melphalan to the liver to treat patients with metastatic cutaneous and ocular melanoma who have unresectable tumors in the liver. The Delcath PHP System™ is designed to deliver significantly higher doses of anti-cancer drugs to a patient's liver while minimizing entry of the drugs into the rest of the patient's circulation. This isolation limits toxicities which result from systemic chemotherapy treatments.

Patients in the Phase III trial are randomized into one of two treatment arms, including immediate treatment with melphalan via the Delcath PHP System™ or treatment with best alternative care. The study is designed to evaluate the duration of tumor response in each of the two study arms. Following guidelines established by U.S. Food and Drug Administration under a Special Protocol Assessment (SPA), patients are permitted to "cross-over" from the best alternative care arm to receive treatment with the Delcath System at the time of disease progression.

About Delcath Systems, Inc.

Delcath Systems, Inc. is a medical device company specializing in cancer treatment. The Company is testing a proprietary, patented drug delivery system for the treatment of liver cancers. Delcath's novel drug delivery platform is testing the delivery of ultra-high doses of anti-cancer drugs to the liver while preventing these high doses of drug from entering the patient's bloodstream. The Company maintains a broad intellectual property portfolio on a worldwide basis including the U.S., Europe, Asia and Canada. 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 our ability to successfully complete Phase III clinical trials and secure regulatory approval of our current or future drug-delivery system 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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