

Edgar Filing: DELCATH SYSTEMS INC - Form DEFA14A

DELCATH SYSTEMS INC
Form DEFA14A
August 21, 2006

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the Securities
Exchange Act of 1934

Filed by the Registrant [X]

Filed by a Party other than the Registrant []

Check the appropriate box:

[] Preliminary Proxy Statement

[] Confidential, for Use of the Commission Only (as permitted by Rule
14a-6(e)(2))

[] Definitive Proxy Statement

[] Definitive Additional Materials

[X] Soliciting Material Pursuant to Section 240.14a-12

DELCATH SYSTEMS, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

[X] No fee required.

[] Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and
0-11.

(1) Title of each class of securities to which transaction
applies:

(2) Aggregate number of securities to which transaction
applies:

(3) Per unit price or other underlying value of transaction
computed pursuant to Exchange Act Rule 0-11 (set forth the
amount on which the filing fee is calculated and state how
it was determined):

(4) Proposed maximum aggregate value of transaction:

Edgar Filing: DELCATH SYSTEMS INC - Form DEFA14A

(5) Total fee paid:

Fee paid previously with preliminary materials.

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

[GRAPHIC OMITTED]

Company Contact:
Delcath Systems, Inc.
M. S. Koly, Chief Executive Officer
203-323-8668
www.delcath.com

Investor Contacts:
Todd Fromer / Garth Russell
KCSA Worldwide
(212) 896-1215 / (212) 896-1250
tfromer@kcsa.com / grussell@kcsa.com

Media Contact:
Lewis Goldberg
KCSA Worldwide
(212) 896-1216
lgoldberg@kcsa.com

FOR IMMEDIATE RELEASE

Delcath Systems Announces a New Site for the Phase III Doxorubicin
Clinical Trial in placeCitySan Antonio, StateTX
- - -

Rohit Kapoor, M.D. Named the Principal Investigator for Study

STAMFORD, Conn., August 18, 2006 -- Delcath Systems, Inc. (NASDAQ: DCTH) ("Company") announced today that the Methodist Health Care System ("Site") has joined Delcath's Phase III clinical trial for the treatment of metastatic

Edgar Filing: DELCATH SYSTEMS INC - Form DEFA14A

melanoma that has spread to the liver, using the Delcath system with Doxorubicin, an approved anti-cancer agent.

The Site, located in San Antonio, TX, has named Dr. Rohit Kapoor, M.D. as the principal investigator to oversee the trial. In addition to the Site's main facility the agreement names The Cancer Center of San Antonio and LabCorp, also of San Antonio, as additional locations participating in recruitment and treatment of patients. The Company has already received the Site's Institutional Review Board (IRB) and budgeting approvals. Delcath has reserved the right to terminate the agreement if the first patient is not enrolled within 90 days, or if two additional patients are not enrolled within five months of the first patient. The Company has notified the U.S. Food and Drug Administration (FDA) about the participation of this Site in the Phase III Doxorubicin trial, which is one of the sites of the 15 permitted to be enrolled in the trial.

The protocol for the Phase III Doxorubicin trial received U.S. FDA approval in 2004. The randomized, multi-center clinical trial will enroll patients diagnosed with metastatic melanoma in the liver. The Company will be looking to demonstrate results that show patients treated with the Delcath system experience statistically longer survival rates versus the control group.

The Methodist Hospital Research Institute has an established history of conducting groundbreaking clinical research and is committed to the advancement of new therapies as rapidly as possible. placeStateTexas has a sizable population of melanoma patients from which to draw upon, providing an ideal proving ground for treatment using the Delcath system with Doxorubicin.

"We are pleased to announce the Methodist Health Care System and its affiliated locations as the first U.S. site for our Phase III Doxorubicin trial. This marks an important milestone for this trial as recruitment is resumed under the guidance of such a highly esteemed placecountry-regionU.S. establishment as Methodist Health Care System. Also, we are very happy that the Doxorubicin trial will be taking place in a different geographical location than our Phase III Melphalan trial, which we believe will increase word-of-mouth, and create greater awareness of the Delcath system," said M.S. Koly, president and chief executive officer of Delcath Systems. "This announcement is further evidence of management's unwavering commitment and ability to recruit sites for the Doxorubicin trial in the U.S. and execute upon its stated business plan. This is a great boost to our efforts and we will continue to recruit new sites for both the Phase III Doxorubicin and Phase III Melphalan trials."

About Delcath Systems, Inc.

Delcath Systems is a developer of isolated perfusion technology for organ or region-specific delivery of therapeutic agents. The Company's intellectual property portfolio currently consists of 12 patents on a worldwide basis, including the country-regionUnited States, Europe, Asia and placecountry-regionCanada. For more information, please visit the Company's website, www.delcath.com.

This 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

Edgar Filing: DELCATH SYSTEMS INC - Form DEFA14A

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. Delcath undertakes no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

On August 1, 2006, Laddcap filed a preliminary consent solicitation statement with the SEC relating to Laddcap's proposal to, among other things, remove the current Board of Directors and replace them with Laddcap's nominees. In response, on August 7, 2006, Delcath filed a preliminary consent revocation statement on Form PREC14A with the SEC (the "Preliminary Consent Revocation Statement") in opposition to Laddcap's consent solicitation. Delcath shareholders should read the Preliminary Consent Revocation Statement (including any amendments or supplements thereto) because it contains additional information important to the shareholders' interests in Laddcap's consent solicitation.

The Preliminary Consent Revocation Statement, the definitive consent revocation materials (when filed) and other public filings made by Delcath with the SEC are available free of charge at the SEC's website at www.sec.gov. Delcath also will provide a copy of these materials free of charge upon request to Delcath Systems, Inc., Attention: M. S. Koly, Chief Executive Officer, (203) 323-8668.

Delcath has engaged MacKenzie Partners, Inc., who may be deemed to be a participant in the solicitation of Delcath shareholders, to assist in connection with Delcath's communications with shareholders regarding Laddcap's consent solicitation. Information regarding the interests of MacKenzie Partners, Inc. is contained in the Preliminary Consent Revocation Statement (including any amendments or supplements thereto). In addition, certain of Delcath's directors, officers and employees may be deemed to be participants in the solicitation of Delcath's shareholders. Information regarding the names and interests of these other persons is contained in the Preliminary Consent Revocation Statement (including any amendments or supplements thereto).

#