## Edgar Filing: DELCATH SYSTEMS INC - Form DEFA14A

DELCATH SYSTEMS INC Form DEFA14A June 12, 2006

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FOR IMMEDIATE RELEASE

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Delcath Systems Responds to Shareholder Proposal; Affirms Commitment to Maximizing Long-term Shareholder Value

STAMFORD, Conn., June 12, 2006 -- Delcath Systems, Inc. (NASDAQ: DCTH), today responded to a recent letter by Robert Ladd, a 10 percent holder of the company's outstanding common stock, filed last week that advocated for his proposal to hire an investment banking firm to be voted on at the company's upcoming Annual Meeting of Stockholders. The Delcath Board of Directors believes that this proposal by Mr. Ladd is shortsighted and goes against the Board's stated objective of maximizing long-term shareholder value.

The Company's response to this shareholder is based on the Board of Director's evaluation of Mr. Ladd, his investment record and what is in the best interest of all shareholders. The Board believes the company will only receive its highest valuation following approval of its drug delivery device by the U.S. Food & Drug Administration. Phase-III trial of the Company's drug delivery device commenced in late February 2006.

Samuel Herschkowitz, M.D., the Chairman of Delcath's Board of Directors, stated, "In the Board's view, Mr. Ladd's letter demonstrates that his strategy all along has been to seek to force a sale of the Company so that he can boost the short-term performance of his own underperforming hedge fund. The Board believes Ladd's proposal would deprive all of the Company's other shareholders of the long-term value of their investments in Delcath. It is also now obvious to us that Ladd's recent campaign of personal attacks on the Company's management and Board have been nothing more than a series of tactics designed to confuse and mislead shareholders in order to further his own selfish interests."

Shareholders who have not voted or wish to change their vote are urged to immediately vote FOR the re-election of the current directors and AGAINST Ladd's self-serving proposal. Shareholders can vote by TELEPHONE or by INTERNET today by following the instructions included in the proxy card previously provided to them by the Company. Every share and every vote counts.

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Inc. toll-free at (800) 322-2885 or collect at (212) 929-5500.

ANNUAL MEETING UPDATE

The company will hold its Annual Meeting of Stockholders Tuesday, June 13, 2006, where M.S. Koly, president and chief executive officer, plans to provide an update on the company's clinical programs.

Currently, five patients have been enrolled and treated in the Phase III study being conducted under a recently awarded Special Protocol Assessment, a binding agreement from the U.S. Food and Drug Administration (FDA). This is a study delivering high dose melphalan, an approved anticancer agent, to the liver for the treatment of metastatic melanoma in the liver. This trial, which is a randomized comparison of isolated perfusion to "Best Available Care", allows for control-arm patients to be crossed over and receive the Delcath treatment if their tumors grow while on the control arm. At least one of the two patients on control who was receiving the best available care has been crossed over to receive the Delcath treatment and all Delcath arm patients are still receiving the experimental therapy. Additional potential patients have been identified who will be evaluated for inclusion into the study in the weeks ahead.

The company plans to discuss the status of Dr. Richard Alexander, Associate Chairman of Clinical Research and Professor of Surgery at the University of Maryland School of Medicine in Baltimore, who has requested to participate in the study. Despite only recently joining the University, Dr. Alexander has assembled a study team, prepared the package for IRB review and placed Delcath in contact with the business office at the prestigious institution. Several additional major comprehensive cancer centers have also indicated an interest in joining the trial, which will effectively enable the company to expedite the patient accrual process.

Mr. Koly is also expected to speak about a parallel Phase II study being conducted utilizing melphalan against three different cancers in the liver: hepatoma, neuroendocrine cancers and adenocarcinomas. Patient accrual in this study is nearly one third complete. While the data in at least one arm of the study indicates strong potential, the company stresses that any data this early in a study is not conclusive.

"We are pleased with the progress we have achieved in our clinical studies," said Mr. Koly. "Our minimally invasive and repeatable form of high dose therapy is designed to improve patient quality of life significantly. We expect to roll-out additional clinical sites in 2006 and remain on course to receive regulatory approval for our unique isolated perfusion technology and commence product commercialization."

About Special Protocol Assessment and Agreement (SPA)

An SPA is a written agreement from the FDA that the Phase III trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval, and can only be granted prior to initiation of the clinical trial. An SPA is binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after testing has begun.

About Delcath Systems, Inc.

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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 United States, Europe, Asia and Canada. For more information, please visit the company's website, www.delcath.com.

This release contains "forward-looking statements" based on current expectations but involving known and unknown risks and uncertainties. Actual results or achievements may be materially different from those expressed or implied. Delcath's plans and objectives are based on assumptions involving judgments with respect to future economic, competitive and market conditions, its ability to consummate, and the timing of, acquisitions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond its control. Therefore, there can be no assurance than any forward-looking statement will prove to be accurate.

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