

DELCATH SYSTEMS INC
Form DEFA14A
September 08, 2006
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

SCHEDULE 14A

(Rule 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant To Section 14(a) of the

Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant S

Filed by a Party other than the Registrant O

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

Soliciting Material Under § 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):

No fee required.

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

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Fee paid previously with preliminary materials.

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(1) Amount Previously Paid:

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

(3) Filing Party:

(4) Date Filed:

Delcath Systems, Inc.

(NASDAQ: DCTH)

The Future of High-Dose Drug Delivery

September 2006

Forward-looking Statements

This presentation 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 3 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. Delcath undertakes no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

Additional Information

On August 17, 2006, Laddcap Value Partners LP (Laddcap) filed a definitive consent solicitation statement with the Securities and Exchange Commission (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 21, 2006, Delcath Systems Inc. (Delcath) filed a definitive consent revocation statement on Form DEFC14A (the Definitive Consent Revocation Statement) with the SEC in opposition to Laddcap s consent solicitation. Delcath shareholder should read the Definitive Consent Revocation Statement (including any amendments and supplements thereto) because it contains additional information important to the shareholders interests in Laddcap s consent solicitation.

The Definitive Consent Revocation Statement 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, Attention: M.S. Koly, President and Chief Executive Officer, (203) 323-8668.

Introduction

- Thank you for this opportunity to speak with you about Delcath Systems
 - We are continuing to make significant progress towards our goal of developing the first approved, repeatable high-dose, organ isolation targeted therapy system
 - We strongly believe that the current board and management team is the right group to fulfill this goal and to continue executing on Delcath's growth strategy
-

Do Not Turn Over Control of Delcath to Laddcap
DO NOT VOTE THE BLUE CARD

The Consent Solicitation

Key Messages From Delcath

- We are absolutely committed to maximizing the value of Delcath over the short- and long-term
- We have never been more excited about the long-term prospects of Delcath
- We have a clear and focused strategic plan that we believe will maximize shareholder returns
- We believe our experience and knowledge of Delcath will be critical to properly overseeing the implementation of the Company s plan
- We believe Laddcap s board nominees and strategic plan will destabilize the Company and introduce substantial undue risk to Delcath and its stock price

We Are Accountable to You For Generating
Strong, Sustainable Value

Key Facts

DELCATH s CURRENT TEAM

- Has delivered superior value to its shareholders compared to the Company s peer group and market indices
- Has almost 50 years of collective experience at Delcath and has significant knowledge and experience regarding the Company s operations
- Has a clear and focused strategy with defined goals for strong, sustainable value creation
- Has been, and will continue to be, absolutely committed to maximizing shareholder value and holding management fully accountable for executing its plan
- Has listened, and will continue to listen, to shareholder proposals and take appropriate actions

LADDCAP

In our view:

- Has been focused on forcing a sale of Delcath for what would be an inferior value only to make a quick profit for his underperforming hedge fund (1)
- Has no discernible expertise in medical devices, clinical trials or running a public company
- Has handpicked a slate of directors with dubious qualifications
- Has a strategy to gain control of the board with no premium to shareholders
- Has a superficial plan that reflects no new ideas and illustrates a poor understanding of Delcath
- Has handpicked a slate of directors that we believe will vote together to execute Ladd s plan

(1) The annual return for Mr. Ladd s hedge fund for 2006 through April 2006 was 5.1%, for all 2005 was -1.7%, and for 2004 was 0.7%, each considerably below the performance of the rest of the market.

Source: Laddcap Value Partners LP April 2006 update to investors. Annual rate for the S&P SmallCap 600 for 2006 through April 2006 was 12.52%, for all 2005 was 6.65%, and for 2004 was 21.59%.

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Laddcap s Takeover Will Harm Delcath

REMOVE:

| Incumbent | Delcath Experience | Background |
|---------------------------|--------------------|--|
| Samuel Herschkowitz, M.D. | 15 years | <ul style="list-style-type: none"> - Former CTO of Delcath for 7 years - Professor at NYU Medical Ctr. - Served on boards of multiple medical and development stage companies |
| M.S. Koly | 18 years | <ul style="list-style-type: none"> - CEO of Delcath since 1998 - Former COO of Repligen - Former Pres. of Becton Dickinson Respiratory Systems - Former Pres. of Hydron Technology |
| Mark Corigliano | 5 years | <ul style="list-style-type: none"> - Founder and owner of a manufacturer and designer of microcomputer systems |
| Daniel Isdamer | 5 years | <ul style="list-style-type: none"> - Founder and director of a development-stage private bank with apprx. \$100mm in assets - Accomplished entrepreneur and real estate developer |
| Victor Nevins | 5 years | <ul style="list-style-type: none"> - Founder and CEO of a highly successful conglomerate - Former trustee of Flushing Hospital and Medical Ctr. |

ADD:

| Nominee | Background |
|---------------------------------|--|
| Robert Ladd | <ul style="list-style-type: none"> - No experience leading a public company - No experience in clinical research - Little experience in healthcare - Manager of a small, underperforming hedge fund |
| Jonathan Foltz | <ul style="list-style-type: none"> - Sued for theft of Delcath trade secrets, unfair trade practices and breach of loyalty - Ladd failed to disclose his economic relationship with Foltz in consent solicitation (1) - Formerly part-time consultant for Delcath |
| Paul William Frederick Nicholls | <ul style="list-style-type: none"> - Filed for personal bankruptcy in 2002 due to debt amassed on credit cards, including credit cards issued by luxury retailers such as Bloomingdale s |
| Michael Karpf | <ul style="list-style-type: none"> - Vice Provost of UCLA Hospital System during a time of generally poor results and relatively |

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high executive compensation

Fred
Zeidman

- Served on audit committee of company that misstated earnings for 7 quarters and filed for bankruptcy (personally named in 7 lawsuits)
- Chairman of company which twice admitted to material weaknesses that subsequently resulted in a restatement of financial statements

We Believe Laddcap s Handpicked Nominees Are Unqualified And
Will Vote To Serve The Short-term Interests Of Laddcap

(1) Until sued by Delcath.

Superior Stock Performance

Relative Performance
October 21, 2001(1) to July 26, 2006

| | Med Tech Small Cap Index- | (22)% | Nasdaq Comp- | 23% | Delcath- | 469% |
|--------|---------------------------|-------|--------------|-----|----------|------|
| Oct 01 | | | | | | |
| Apr 02 | | | | | | |
| Oct 02 | | | | | | |
| Apr 03 | | | | | | |
| Oct 03 | | | | | | |
| Apr 04 | | | | | | |
| Oct 04 | | | | | | |
| Apr 05 | | | | | | |
| Oct 05 | | | | | | |
| Apr 06 | | | | | | |

(1) Delcath s current independent board members joined the Company on October 21, 2001

Your Board of Directors And Management Team Have An
Outstanding Track Record Of Value Creation

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Laddcap s Poor Track Record (1)

Laddcap Value Partners Holdings

Delcath 40%
Other Holdings 60%

Almost 40% of Laddcap s fund is invested in one stock - Delcath

LaddCap Fund vs. S&P SmallCap 600

Return

25.0% 20.0% 15.0% 10.0% 5.0% 0.0% (5.0%)

| | 2004 | 2005 | 1/2006 - 4/2006 |
|------------------------|-------|--------|-----------------|
| Laddcap Value Partners | 0.7% | (1.7%) | 5.1% |
| S&P SmallCap 600 | 21.6% | 6.7% | 12.5% |

The annual performance of Laddcap s fund has been substantially lower than the market

Protect Your Investment -
Don t Let Laddcap Make Its Problems Yours

(1) Source: Laddcap Value Partners LP April 2006 update to investors.

We Are Listening And Responding To You

In response to shareholder proposals, we recently announced the following:

- Initiated a search for two new board members who meet our governance standards and strengthen key skill sets, and remain on track to have one new director in place by the end of the third quarter
- Hired a nationally recognized investment bank to provide strategic advisory services
- Implemented a more robust shareholder communication plan to provide more frequent and timely updates on our progress
- Expanded Delcath s investor and public relations campaigns to raise the Company s profile among investors, clinicians, hospitals and academic institutions

We Are Dedicated To Implementing Standards To Promote Good Corporate Governance

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Delcath Accomplishments

-
- | | |
|-------------------|---|
| NCI Collaboration | <ul style="list-style-type: none">- Developed a deep, long-standing relationship with the National Cancer Institute (NCI)- Obtained the NCI s sponsorship as the lead site for the Melphalan Phase 3 trial- Leveraged the NCI s decade-long work on high dose liver therapy |
|-------------------|---|
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| Fast Track Designation | <ul style="list-style-type: none">- Received fast-track designation in April 2005- Expected to facilitate development and expedite the review of the Delcath system |
|------------------------|--|
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|-----------------------------|---|
| Special Protocol Assessment | <ul style="list-style-type: none">- Established, in conjunction with FDA, a viable Phase 3 trial protocol in February 2006- Expected to reduce time to approval- Solved the control arm issue by allowing crossover from control arm to treatment arm |
|-----------------------------|---|
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| Addition of New Sites | <ul style="list-style-type: none">- Announced on August 18 the addition of a new site in the Doxorubicin Phase 3 trial- Made significant progress in recruiting the Univ. of Maryland for the Melphalan Phase 3 trial- Discussions with U.S. and ex-U.S. medical centers to participate in the Doxorubicin Phase 3 trial |
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| Research & Development Progress | <ul style="list-style-type: none">- Successfully recruiting and enrolling patients in Delcath s three ongoing Phase 2 and 3 trials- Enrolled 75% of total patients in the Phase 2a trial in adenocarcinoma and 60% of total patients in the Phase 2a trial in neuroendocrine cancer- Ongoing dialogue investigating additional organs and drug combinations |
|---------------------------------|---|
-

The Delcath Strategy

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Delcath s Goals and Strategy

GOALS

STRATEGY

Operational

Complete Ongoing Studies

- Work closely with NCI to add additional sites for Melphalan Phase 3 trial
- Aggressively seek additional sites for Doxorubicin Phase 3 trial
- Support NCI Phase 2 neuroendocrine, adenocarcinoma and hepatocellular trials

Initiate New Studies

- Continue discussions with the NCI about testing feasibility of HCV treatment
- Identify corporate partners to fund trials in other organs

Develop Next Generation Filters

- Work with current supplier to develop next generation filters

Non-Operational

Enhance Corporate Governance

- Work with nominating committee comprised of independent directors to identify and recommend new director candidates
- Continue to review corporate governance guidelines to ensure best practices

Increase Profile of Delcath

- Provide shareholders with regular quarterly updates
- Work with C.E. Unterberg, Towbin to increase exposure to institutional investors, research analysts and investor conferences

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Near-term Milestones

GOALS

NEAR-TERM MILESTONES

Operational

- Complete Ongoing Studies - NCI multi-center decision on Melphalan Phase 3 trial in September
- Complete Melphalan Phase 3 trial by end of 2008 (assuming three s
- Complete Phase 2a Melphalan studies in Q1 and Q2 2007

Initiate New Studies

- 2007 - Identify partner to fund clinical trial in Hepatitis C

Identify Filter Partner

- 2007 - Begin production of next generation filter

Non-Operational

- Add one new director to board by end of Q3 2006

Enhance Corporate Governance

- Add second new director to board by end of 2006
- Conduct quarterly updates within 30 days after quarter end and 45 after year end

Increase Profile of Delcath

- Attend C.E. Unterberg, Towbin Annual Life Science Investor Confer October 2006
- Conduct two investor roadshows by end of 2006

Deep Relationship with the NCI

- The Delcath management team has developed a very close relationship with the NCI over the past six years
 - NCI has studied high dose liver therapy for more than 10 years
 - NCI approached Delcath for clinical study partnership
 - NCI Principal Investigator wanted to lead a pivotal trial that could result in FDA approval
-

NCI Reports on Delcath System

H. Richard Alexander, M.D.

Associate Chair for Clinical Research
University of Maryland

Former Head of Surgical
Metabolism Section of the
National Cancer Institute

Text of Sound Clip by Richard Alexander M.D.:

Our interest in isolated perfusion started about eight years ago when there were a number of clinical trials evaluating various forms of regional therapies focused to the liver for individuals who had progressive unresectable cancers confined to that organ and that happens to be a significant clinical problem in this country. A large number of individuals with colorectal cancer for example will ultimately develop this problem and patients with other histologies will also develop the problem. So we looked at refining a technique that had been established long before we started this program of isolated hepatic perfusion in which basically the liver is physically prepared during an operative procedure and then catheters are inserted into the blood vessels going in and out of the liver then the catheters are connected to a heart lung machine and then when the machine is turned on we can deliver through the liver very high doses of anti-cancer agents to try and control the condition in the liver. Now our initial results with that kind of a program were very encouraging and we were able to see fairly significant reduction in the size of tumors often lasting for a considerable period of time in people who had very advanced and previously treated tumors. I think the major downside is that it is a major operative procedure it has certain risks attendant with it and it can only be done one time. Once it is done, because of the scar tissue that develops around the liver, particularly in the spots where we need to place our catheters it can only be done one time. So we were looking for another mechanism by which we could focus therapy into the liver that might be a little bit more straight forward for any individual to undergo, so the Delcath System is a perfect, in my view, a perfect application to try and determine whether or not we can deliver a high dose melphalan using a less invasive technique than a major operative procedure.

It is possible with the Delcath System that patients could undergo treatments for potentially many months and in particular effects ratio that the tumors are in fact regressing after one or two therapies there is no reason why they couldn't undergo two or three or four more additional treatments in order to continually cause the tumors to regress. So I think the Delcath System has the beauty of being repeatable and I think it is a little bit more straightforward for any individual to get through.

There had been in the biomedical research community a long standing interest in identifying a technique, whether it be a physical technique or using gene delivery systems or other kinds of methods to hone a therapy directly to the tumor and I think that right now there have been no one kind of mechanism that has emerged to be so effective and superior that everyone is looking at that as the most promising avenue to pursue. So I look at physical methods of delivering therapies to cancer bearing regions of the body as valid as any of the others that might be considered more sophisticated techniques because they all have, when it ultimately comes down to medical practice, they all have a lot of issues that prevent them from being as effective as you would anticipate based upon theoretical consideration. I think that with the Delcath System, although it seems kind of a basic and more of an elementary method the realities are that it probably has as good of likelihood as any to focus a treatment to an important part of the body to intensify treatment.

Laddcap s Success Will Be To Delcath s Detriment

The following are excerpts from an August 11, 2006 letter written by Dr. Alexander to M.S. Koly:

I am concerned that a change in leadership or management of the company at this point in time may have significant deleterious consequences on the continued timely evaluation of Delcath Systems technology.

If the senior management were to be replaced it would require me to reassess any involvement with the company.

Over the course of the last six years I have found you and other representatives of the company to be extremely professional, competent and committed to supporting the highest standards of clinical research.

NOTE: Underlines added for emphasis.

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Summary of Ongoing Phase 3 Trials

| | Melphalan | Doxorubicin |
|--------------------|---|--|
| Start Date | April 2005 | June 2004 |
| Controlling Entity | NCI | Delcath |
| Indication | Melanoma Liver Metastases | Melanoma Liver Metastases |
| Number of Patients | 92 | 122 |
| Inclusion Criteria | Refractory to all therapies | Refractory to all therapies |
| Endpoint | Time to Progression | Survival |
| Control Arm | Best Alternative Therapy Crossover Allowed | Dacarbazine No Crossover Allowed |
| Status | Fast Track Granted Special Protocol Assessment | New site added on 8/18/06 Ongoing discussions w/ IRBs |

Strong Development Pipeline

| | 2006 | | 2007 | | 2008 | | 2009 | |
|---|------|----|------|----|------|----|------|--------------|
| | 3Q | 4Q | 1H | 2H | 1H | 2H | 1H | 2H |
| PHASE 3 MELPHALAN | | | | | | | | |
| NCI Multi-Center Decision Patient Enrollment | | | | | | | | |
| | | | | | | | | File NDA/PMA |
| PHASE 3 DOXORUBICIN | | | | | | | | |
| Discussions w/ New IRBs Patient Enrollment | | | | | | | | |
| OTHER INDICATIONS | | | | | | | | |
| Neuroendocrine & Adeno. | | | | | | | | |
| Phase 2a | | | | | | | | |
| | | | | | | | | Phase 2b |
| | | | | | | | | Phase 3 |
| Hepatocellular. | | | | | | | | |
| Phase 2a | | | | | | | | |
| | | | | | | | | Phase 2b |
| | | | | | | | | Phase 3 |

Conclusions

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What Happens Next Is Up To You

| | | | | |
|----------------|----------------|-----------------|-------------------|--------|
| 10/17/05 | | | | 7/ |
| Laddcap files | April 2006 | | 6/7/06 | La |
| 13D stating it | Laddcap | 6/4/06 | Fulcrum and | wit |
| may cause sale | announces poor | Fulcrum goes | Glocap issue | requ |
| of Delcath | fund returns | out of business | valuation opinion | specia |

| | | | | |
|------------------|------------------|---------------|-------------------------------|------------|
| 1/5/06 | 4/27/06 | 6/27/06 | 7/27/06 | 8/ |
| Laddcap proposes | Laddcap | Delcath | Laddcap delivers written | Laddcap fi |
| hiring an | requests special | announces it | consent to Delcath; Mr. Foltz | solicitati |
| investment bank | meeting | will add two | resigns, and on the same day, | with |
| | | new directors | shows up on Laddcap s slate | |

Observations:

- Although Laddcap has put the Company in play and been relentlessly calling for a sale for almost a year, not one party has approached Delcath with interest in a merger or acquisition
- Before 8/1/06, Laddcap s only strategic suggestion was: engage an investment bank
- Based on a valuation from Fulcrum, which closed its investment banking business PRIOR TO issuing its opinion, Laddcap believes a fair value for a sale of Delcath could be as little as \$6.65 per share. WE DO NOT AGREE
- Despite steps taken by Delcath to adopt certain of Laddcap s proposals and engage in constructive dialogue, it appears Laddcap will accept nothing less than a takeover of Delcath

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during the balance of fiscal year 2006, establish at least two additional sites for Delcath's ongoing Phase 3 trial using Melphalan

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A Sale Today Will Not Maximize Value

Impact of Commercial Scale on Valuation
 Medical Technology Acquisitions: 1996 - 2006 (1)

Median Transaction Value

| \$600 | \$500 | \$400 | \$300 | \$200 | \$100 | \$0 |
|-----------------|-------|-------|---------------|-------------|--------------|---------|
| No Revenue | | | \$0 - \$10 | \$10 - \$50 | \$50 - \$100 | > \$100 |
| \$17 | | | \$9 | \$48 | \$115 | \$485 |
| 1 | | | 77 | 55 | 22 | 21 |
| | | | Revenue Range | | | |
| Median Revenue: | | | \$4 | \$22 | \$71 | \$242 |

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Observations:

- o Only one medical technology company with no revenue was acquired in the last 10 years (1)
- o The median enterprise value for medical device companies with less than \$10 million in revenue is only \$9 million (1)
- o Delcath is currently trading at an equity value of almost \$80 million

Given Our Stage Of Development And Current Valuation, It Is Highly Unlikely That Potential Acquirors Will Be Interested in Delcath Today

(1) Source: Factset Mergerstat. Includes all medical device companies with disclosed financial information and transaction values

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Impact of Commercialization on Valuation

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Edgar Filing: DELCATH SYSTEMS INC - Form DEFA14A

Do NOT Vote The BLUE Card

IF YOU ARE...

FOR

Continued Execution on Delcath s Growth Plan - the Delcath Board is committed to bringing the Company s revolutionary technology to market and holding management accountable for its performance

An Experienced and Knowledgeable Board - the Delcath Board has approximately 50 years of combined experience at the Company

Two New Independent Directors - who will be added before the end of 2006 and will strengthen key skill sets

Sustainable Value Creation - strong price momentum is expected to continue as Delcath advances its clinical programs

AGAINST

Laddcap s Unqualified Slate of Nominees - who have dubious qualifications and little-to-no experience with public, development stage, healthcare companies

Laddcap s Flawed Strategic Plan - which demonstrates a lack of understanding of Delcath s business, offers no new ideas

Laddcap s Selfish Agenda and Handpicked Bloc of Nominees - that will only serve to force a sale of Delcath at an inferior value

Introducing Undue Risk - A change in leadership will completely destabilize Delcath, delay its clinical progress and undo years of progress made by the Company

...DISCARD THE BLUE CARD AND VOTE THE GOLD CARD.

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Delcath Systems, Inc.

(NASDAQ: DCTH)

The Future of High-Dose Drug Delivery

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(203) 323-8668

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