

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): July 27, 2009

DEL CATH 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 communications 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 July 27, 2009, Delcath Systems, Inc. (the "Company") issued a press release regarding a previously noticed quarterly update conference call. The call will be archived and made available shortly on the Company's website, www.delcath.com. On the call the Company announced, among other things, that it has been granted FDA approval to increase the number of centers that may participate in the Company's trials to a maximum of 28 centers. It was also announced that since late April the Company has enrolled an additional 18 patients, with enrollment currently at 79 patients, and has screened 40 additional patients for enrollment. It was further announced that the Company has received orphan-drug designation for the drug melphalan for the treatment of patients with neuroendocrine tumors. A copy of the press release dated July 27, 2009 regarding the conference call and the transcript of the conference call are attached hereto as Exhibit 99.1 and 99.2, respectively, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of Delcath Systems, Inc., dated July 27, 2009
99.2	Transcript of July 27, 2009 Conference Call

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: July 27, 2009

DELCATH SYSTEMS, INC.

By: /s/ Eamonn Hobbs

Name: Eamonn Hobbs

Title: Chief Executive Officer



Approved By:

Eamonn Hobbs
President & CEO
212-489-2100

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FOR IMMEDIATE RELEASE

DEL CATH SYSTEMS PROVIDES UPDATE ON PROGRESS
***Patient Enrollment in Phase III Metastatic Melanoma Trial Now at 79
Conference Call to Discuss Second Quarter Results Today at 4:30 PM EST***

NEW YORK, NY, July 27, 2009---Delcath Systems, Inc. (Nasdaq: DCTH), a medical technology company developing a minimally invasive drug delivery platform for the regional treatment of cancer metastatic to the liver, today reported on the Company's recent progress. In addition, the Company reported its financial results for the second quarter ended June 30, 2009.

Recent Highlights

- Screened 40 Additional Patients for Enrollment in Phase III Metastatic Melanoma Trial
 - Since Late April, Enrolled an Additional 18 Patients in Trial
 - Total Trial Patient Enrollment Now at 79
 - 12 Total Participating Centers; FDA Grants Approval to Increase Maximum Number of Centers Enrolling Patients to 28
 - Received Orphan Drug Designation for the Drug Melphalan for the Treatment of Patients with Neuroendocrine Tumors.
 - Accomplished Medical Device Executive Eamonn Hobbs Appointed President & CEO
 - Cash as of June 30, 2009 at \$8.9 Million
 - Company Invited to Present at 29th Annual Canaccord Adams Global Growth Conference on August 13, the Rodman & Renshaw Annual Global Investment Conference on September 10-11 and Maxim Group Growth Conference on September 29.
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- Delcath's PHP System™ scheduled to be included in presentations at The Liver Symposium on August 22 in Denver, the Western Angiographic and Interventional Society Meeting on August 29-September 2 in La Jolla, and the National Carcinoid/Neuroendocrine Tumor Patient Conference on September 24-26 in New Orleans.

“During the past few months, we continued to achieve patient enrollment milestones in our Phase III Metastatic Melanoma Trial. Based on recent trends, we continue to be optimistic about completing enrollment of 92 patients in this trial before the end of the fourth quarter,” commented Mr. Hobbs. “The patient enrollment progress has made me even more excited about the potential for Delcath. Our drug delivery platform is unique in the interventional oncology space. We have the potential to address a large and growing unmet medical need with our technology and I look forward to completing our Phase III trial and submitting for FDA approval in a timely manner. Meanwhile, we’ve been focusing on expanding the awareness of our technology within the medical and professional communities and expect to add more presentations as we move into the fall,” Mr. Hobbs added.

Financial Results

During the second quarter of 2009, Delcath Systems recorded no revenue. General and administrative expenses declined 22% as compared to the second quarter of 2008 due to reduced consultant fees. R&D costs doubled to \$2.2 million from \$1.1 million in the second quarter of 2008 due to costs associated with the Phase III Metastatic Melanoma Trial. The Company recorded a derivative instrument expense in the second quarter of \$3.9 million related to warrants issued in 2007 and 2009. The net loss for the quarter was \$6.3 million, or \$0.25 per share, compared with \$2.4 million or \$0.10 for the second quarter of 2008, an increase of \$3.9 million, of which \$3.3 million was related to non-cash derivative instrument expense.

For the six months ended June 30, 2009, the net loss was \$8.8 million, or \$0.34 per share, versus a net loss for the first six months of 2008 of \$3.5 million, or \$0.14 per share, an increase of \$5.3 million of which \$4.5 million is related to non-cash derivative instrument expense. As of June 30, the Company had cash and cash equivalents of \$8.9 million.

Conference Call

Delcath Systems will host a conference call and webcast today, **Monday, July 27, 2009 at 4:30 p.m. Eastern / 1:30 p.m. Pacific** to discuss the Company's recent progress. The dial-in number for the conference call is 877-941-0844 for domestic participants and 480-629-9645 for international participants.

A taped replay of the conference call will also be available beginning approximately one hour after the call's conclusion and will be available for seven days. This replay can be accessed by dialing 800-406-7325 for domestic callers and 303-590-3030 for international callers, both using passcode 4117854#. To access the live webcast of the call, go to Delcath's website at www.delcath.com. An archived webcast will also be available at www.delcath.com.

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 is currently enrolling patients in Phase III and Phase II clinical studies for the treatment of liver cancers using high doses of melphalan. The Company's intellectual property portfolio consists of twenty-seven patents 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.

(tables to follow)

DEL CATH SYSTEMS, INC.
(A Development Stage Company)

Condensed Balance Sheets

	June 30, 2009	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	\$ 7,435,673	\$ 6,939,233
Investments - CDs	1,472,928	3,847,904
Investments - treasury bills	—	200,710
Investments - marketable equity security	36,000	22,000
Income Tax Receivable	298,535	—
Prepaid expenses	324,253	331,346
Total current assets	<u>9,567,389</u>	<u>11,341,193</u>
Property and equipment, net	<u>14,558</u>	<u>17,489</u>
Total assets	<u>\$ 9,581,947</u>	<u>\$ 11,358,682</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	\$ 344,083	\$ 703,489
Derivative instrument liability	7,105,454	448,318
Total current liabilities	<u>7,449,537</u>	<u>1,151,807</u>
Commitments and contingencies	—	—
Stockholders' equity		
Common stock, \$.01 par value; 70,000,000 shares authorized	262,530	253,834
Additional paid-in capital	58,019,453	57,343,507
Deficit accumulated during development stage	(56,088,270)	(47,315,163)
Treasury Stock	(51,103)	(51,103)
Accumulated other comprehensive loss	(10,200)	(24,200)
Total stockholders' equity	<u>2,132,410</u>	<u>10,206,875</u>
Total liabilities and stockholders' equity	<u>\$ 9,581,947</u>	<u>\$ 11,358,682</u>

Delcath Systems, Inc.
(A Development Stage Company)
Condensed Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Costs and expenses:				
General and administrative expenses	\$ 544,913	\$ 699,136	\$ 1,019,876	\$ 1,140,140
Research and development costs	2,195,036	1,099,488	3,656,226	2,088,444
Total costs and expenses	<u>2,739,949</u>	<u>1,798,624</u>	<u>4,676,102</u>	<u>3,228,584</u>
Operating loss before taxes	(2,739,949)	(1,798,624)	(4,676,102)	(3,228,584)
Derivative instrument income (expense)	(3,904,379)	(671,652)	(4,466,157)	(473,401)
Interest income	18,167	50,002	68,928	223,965
Other income	-	-	1,689	-
Interest expense	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
Net loss before tax benefit	(6,626,161)	(2,420,274)	(9,071,642)	(3,478,020)
Income tax benefit	298,535	-	298,535	-
Net loss	<u>\$ (6,327,626)</u>	<u>\$ (2,420,274)</u>	<u>\$ (8,773,107)</u>	<u>\$ (3,478,020)</u>
Common share data:				
Basic and diluted loss per share	<u>\$ (0.25)</u>	<u>\$ (0.10)</u>	<u>\$ (0.34)</u>	<u>\$ (0.14)</u>
Weighted average number of shares of common stock outstanding	<u>25,528,282</u>	<u>25,262,031</u>	<u>25,455,818</u>	<u>25,260,658</u>

DEL CATH SYSTEMS, INC., #4117854
DEL CATH SYSTEMS, INC. –
SECOND QUARTER 2009 FINANCIAL RESULTS
July 27, 2009, 4:30 PM ET
Chairpersons: Doug Sherk, Eamonn Hobbs (Mgmt.)

Operator: Ladies and gentlemen, thank you for standing by, and welcome to the Delcath Second Quarter 2009 Financial Results Conference Call. During today's presentation, all parties will be in a listen-only mode. Following the presentation, the conference will be opened for questions. If you have a question, please press the star followed by the one on your touchtone phone. If you would like to withdraw your question, please press the star followed by the two. And if you're using speaker equipment, please lift your handset before making your selection. This conference is being recorded today, Monday, July 27th, of 2009.

And at this time, I would like to turn the conference over to Doug Sherk. Please go ahead, sir.

Doug Sherk: Thank you, Operator. And good afternoon, everyone, and thank you for joining us for Delcath Systems' Second Quarter Conference Call. With me today is Eamonn Hobbs, the President and Chief Executive Officer of the Company—I should say, newly appointed President and Chief Executive Officer of the Company, and Board member, Richard Taney. In addition, Jason Rifkin, Senior Vice President of Clinical Operations, and Barbra Keck, Controller, are joining us today. During today's call, they will discuss the Company's progress since the last call in late April as well as other relevant business updates. A taped replay of the conference call will be available beginning approximately one hour after the call's conclusion and will be available for seven days. This replay can be accessed by dialing 800-406-7325 for domestic callers and 303-590-3030 for international callers. Both numbers require the passcode 4117854 followed by the pound sign. Today's call is also being webcast live via the Company's website at www.delcath.com, and the call will also be archived on the website.

Before we begin, let me quickly reference the Private Securities Litigation Reform Act of 1995, which provides a safe harbor for forward-looking statements made by the Company. Today's call may contain forward-looking statements which are subject to certain risks and uncertainties, 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 the Company's ability to successfully complete Phase III clinical trials and secure regulatory approval of current or future drug delivery systems and uncertainties regarding the ability to obtain financial and other resources during research, development, and commercialization activities. These factors and others are discussed and found in timely 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. The Company has no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

With that, I'd like to turn the call over to Rich Taney.

Rich Taney: Thank you, Doug. Good afternoon, everyone. I want to begin by thanking our loyal shareholders for joining us today. It has been thrilling to lead Delcath into its current state and impressive to see how the Company has progressed over the past two-and-a-half years. We are at an exciting time in the life of Delcath. When I first took over the day-to-day leadership responsibilities of the Company, the Board and I both recognized that for Delcath to maximize shareholder value, there would come a time to transition the Company's leadership to someone with an established track record of commercialization in the medical device industry, proven relationships with clinicians and thought leaders, and proven ability to successfully launch a new medical technology into the marketplace. We also recognize that two-and-a-half years ago, the circumstances limited our ability to attract a leader with those qualities. Since then, Delcath has made tremendous progress. In July, we decided that the time was right to bring on the leader the Company needed to take Delcath to the next level, and we asked Eamonn to accept our offer to expand his role from Board member to President and CEO. We are delighted that he did just that.

Eamonn has served on Delcath's Board of Directors since October of 2008. During his career, he has started two medical device companies, and he has identified, developed, and brought to market numerous devices. In addition, he is an Honorary Fellow of the Society of Interventional Radiology and is on the organization's Strategic Planning Committee. Eamonn is also a member of the Society of Cardiovascular and Interventional Radiology and sits on the Board of Directors of the Medical Device Manufacturers Association, the Society of Interventional Radiology Foundation, and the American College of Phlebology Foundation. The relationships Eamonn has developed through these activities will benefit Delcath as we move toward commercialization, and I look forward to Delcath's success under his leadership.

So, with that brief introduction, I'd like to turn the call over to Mr. Eamonn Hobbs, President and CEO of Delcath Systems.

Eamonn Hobbs: Thank you, Rich, for that very gracious introduction. I echo Rich's thanks to our loyal shareholders for their continued support as we move through this exciting time, and thank you all for joining us for a review of our recent progress.

Since the last conference call in late April, our shares have risen by approximately 30%, and we've been included in the Russell 3000 and Russell 2000 Indexes. Because we have a number of new shareholders, I'd like to begin today with a brief overview of what I see as the Delcath opportunity. Then, we'll walk through our recent developments and take your questions.

The Delcath opportunity begins with the market. We believe the regional oncology therapy market is large and untapped, with an annualized sales opportunity estimated to be approximately \$3 billion. To address this market opportunity, Delcath has developed what I believe is a superior system that is currently undergoing clinical evaluation at 12 leading cancer centers in the United States. The Delcath System has, to date, been generating successful results in clinical trials, and patient enrollment in our Phase III metastatic melanoma trial is building. Another key element to the Delcath opportunity is that Delcath retains worldwide rights to the PHP System, and our technology is protected by 27 patents. And, finally, since the Delcath PHP System is a platform technology, I see great potential for its extension to treat cancer in other organs and body regions, including use in patients with primary liver cancer (HCC), metastatic colorectal cancer, and neuroendocrine tumors and other metastatic cancers. In addition, I look forward to testing the device in patients with infectious diseases such as hepatitis C virus. I am looking forward to leveraging my relationships within the medical community and delivering this exciting treatment modality to oncology patients worldwide. We have a lot of hard work ahead of us, but I view the Delcath opportunity as having huge potential, and I look forward to working with the team and the Board to fully capitalize on that opportunity.

Let me now take you through the recent highlights. As I mentioned, patient enrollment in our Phase III metastatic melanoma trial is building. At our annual meeting in June, we announced that enrollment had passed the 75th percentile, and as of today, enrollment has further increased to 79 patients. We remain on target to complete enrollment of 92 patients in our Phase III metastatic melanoma trial before year-end of 2009. Of those patients, 38 have been randomized to receive the Delcath PHP treatment, and 41 have been randomized to receive best alternative care. Of those 79 patients, 41 were treated at the National Cancer Institute, and another 38 patients were treated at other clinical centers around the United States. Since our last call with you in late April, we have screened 40 potential Phase III melanoma patients in addition to the 18 new patients who were found to be eligible and have enrolled in the trial. Increased patient and clinician awareness of the Delcath System is one factor behind the growth in enrollment, and a major factor behind the increased awareness is the recent media coverage of our treatment's benefits to patients. Just last month, CNN profiled a patient who had been treated by our system, and this tremendous coverage followed up earlier reports on ABC News, the Associated Press, and a television station in Denver. By the way, all of these stories are on our website. The patients are being enrolled in 12 centers currently participating in the trial. The FDA recently granted us the approval to increase the maximum number of centers in our trials to 28. However, given the recent enrollment momentum, we don't at this time expect to expand in center participation beyond 15. We still believe we can complete enrollment in the Phase III trial before the end of the year. And if that schedule holds, we would expect to file with the FDA by mid-2010 and to gain CE Mark approval, which would allow for marketing outside the U.S.A. by June 2010.

In addition to completing enrollment in the Phase III trial, there will be other milestones we need to meet before we file with the FDA. One was the submission of our safety data to our DSMB upon reaching the 75th percent of enrollment milestone. The DSMB is scheduled to meet on September 10th to review the safety data.

Finally, I'd like our listeners today to know that we'll be presenting at the Canaccord Adams Global Growth Conference in Boston on Thursday morning, August 13th. In addition, we've been invited to present at the Rodman & Renshaw Global Investment Conference, which will be held September 10th and 11th in New York, and on September 29th, we will present at the Maxim Group Growth Stock Conference in September. We are also scheduling meetings with investors around the country over the next few weeks, and if you'd like to meet, please let the folks at the EBC Group know.

Those are my prepared remarks for today. Operator, we're now ready to take questions.

Operator: Thank you, sir. Ladies and gentlemen, we will now begin the question and answer session. As a reminder, if you have a question, please press the star followed by the one on your touchtone phones. If you'd like to withdraw your question, please press the star followed by the two. And if you are using speaker equipment, please lift your handset before making your selections. Once again, if you wish to ask a question, please press the star followed by the one.

Our first question comes from the line of Jason Mills with Canaccord Adams. Please go ahead.

Jason Mills: Hi. Thanks for taking the call, and good afternoon, Eamonn, Rich, and Jason.

Eamonn Hobbs: Hi, Jason, how are you?

Jason Mills: Good to hear your voice on a conference call again, Eamonn.

Eamonn Hobbs: Thank you very much.

Jason Mills: Look forward to hearing more of it. Thanks for the update. I guess, the first question is, during the Phase III clinical trial insofar as you're able to help us out with this, do you have a sense for the patients that are crossing over to the PHP arm at this point, any update there?

Eamonn Hobbs: So far, 18 patients have crossed over out of the 41, in the BAC arm, and that shows us two things. One, that patients in the BAC arm are progressing and thereby qualifying for crossover.

Jason Mills: Not surprising, I would guess, from your standpoint.

Eamonn Hobbs: Not at all.

- Jason Mills: Right. Then, you mentioned 12 centers participating during the quarter, you expect to expand to 15. As Rich and I have talked about for the last year or so, the pace of new centers coming on board has been quite impressive over the last 12 months. It took a little while to get over the hump, Rich, but once you did, it seemed to be that the floodgates have opened. I'm wondering, have you identified the three additional centers you plan to start the program? And I'm just wondering beyond that, if you've actually identified the additional 13 that perhaps may not get involved in this trial but could be involved in further studies down the line?
- Eamonn Hobbs: Yes, we've definitely identified those. We have yet to choose the next three. We have a long list that we're negotiating with. And, you know, our current feeling is that it's likely that three more will come on before the end of the trial, but the additional centers on the list will be candidates for future trials, as we don't want to get them started and then run out of pivotal trials to work with them on.
- Jason Mills: Right, and it also costs money to open the centers, as Rich has talked about in the past. So, with respect to additional trials, perhaps, Eamonn, you could spend a minute and help us, give us more color with respect to your strategy as it relates to some of the other disease states that you talked about in your opening remarks, and your strategy as it relates to addressing the—those with the system moving forward in terms of partnerships or however you would see was the most prudent and effective to address, all the different opportunities that you mentioned.
- Eamonn Hobbs: I see the Delcath PHP System as, really, an extremely broad platform technology that has potential applications in treating additional diseases of the liver, additional cancers like colorectal, primary liver, neuroendocrine, but also for other organs where cancer can be treated, like the kidneys, the lungs, potentially brain, pelvis and, outside of cancer, the ability to treat infectious diseases, like hepatitis C, as we've talked about. So, there's a real broad spectrum of opportunities to pursue additional indications. And our strategy to pursue those indications is really tied to three legs. The first leg is to have a laser-like focus to get our first approved indication for malignant melanoma mets to the liver and become a commercially viable company selling devices. We're going to do that with our CE Mark for OUS markets about the middle of next year, we should start commercial operations outside the U.S., and in the U.S, approximately a year thereafter, with the gaining of FDA approval. The other two legs, really, are associated with again, teaming up with strategic partners who we will work with to pursue additional indications and open up the platform. So, at this time, we're very actively involved with both domestic potential strategic partners that are primarily pharmaceutical companies who have stables of chemotherapeutic agents that we can dramatically enhance the performance and market status as well as OUS potential partners, especially, in the Asian markets where most of the diseased livers in the world reside, and those would be China, Korea, and Japan.

So, the three legs, again, are commercialization of the PHP device system, first to OUS and then U.S., and then domestic partnerships with a very strong strategic handle to them, and then OUS partnerships, especially in Asia.

Jason Mills: Got it, that's helpful. With respect to your OUS strategy, upon CE Mark approval, you're modeling mid-2010, what is your strategy to address the market there in terms of your distribution, and then also, part and parcel to that, perhaps you could give us an update on your manufacturing strategy as you enter the commercial stage, obviously, you've got to be thinking about scaling up?

Eamonn Hobbs: Yes, well, as far as the OUS distribution, we're going to be looking for strategic partners that are well suited to distribute the Delcath System in selected OUS marketplaces as well as being capable of expanding the indications that the system is utilized and approved for. So, we're already in the process of identifying those partners who will ultimately either facilitate distribution or will actually be the distributor, and I see that I think we have plenty, ample time to get all that set up by the middle of next year when we're ready to begin distribution operations.

With regard to the scale-up, we are transitioning from being a developmental stage company to an operational one, which means we need to create operational facilities for manufacturing, distribution, sales and marketing, first for OUS markets and then domestic. And that process is underway, and I would expect that we will be opening an operations facility prior to, well before the end of the calendar year.

Jason Mills: Okay, that's helpful. One more, and I'll get back in queue. Your cash burn seems to be about on par with what the Company reported in Q1. Should we expect sort of this level going forward?

Eamonn Hobbs: I would expect, as we start to ramp up operations, there'll be an increase in our burn. We're still calculating that, but as you can well imagine, bringing on an operations and distribution, and sales and marketing is going to increase our burn rate.

Jason Mills: Right, and that will start to show up in the third quarter, or the way I took it was, that would be sort of as you get closer to finishing enrollment?

Eamonn Hobbs: Definitely, it's going to start to show up in the third quarter.

Jason Mills: Okay. Very helpful. Thanks, guys.

Eamonn Hobbs: Thank you, Jason.

Operator: Thank you. Our next question comes from the line of Yale Jen with Maxim Group. Please go ahead.

Yale Jen: Good afternoon. It seems to be a very good start here. And listening here to the stories, I'd like just to start with the DMSB meeting. So, you anticipate in September, what would the expect—what was expected to be reviewed by DMSB meeting in this—in this time, is just, purely the safety, or there's more to it?

Eamonn Hobbs: Well, the DSMB meeting is a routine meeting that will be held September 10th where the data from the trial will be reviewed for a number of aspects. The first and foremost, of course, is safety, and other considerations that the DSMB will take into account are the power that is coming out of the study so far, that's—is, for instance, the study already reached a level of statistical significance, and then there could be a recommendation to—that the study is completed and there's no reason to continue to randomize patients. Is there anything else they're doing, do you think the DSMB would do, Jason?

Jason Rifkin: No, as Eamonn said, just based on the toxicity, the safety, that's really their primary focus.

Yale Jen: Okay, great. And should I assume this will be the last DMSB meeting before completing enrollment?

Jason Rifkin: That's correct.

Yale Jen: And do you guys think any—think about any possibility that you could start this—the trial early, or too early to think about that at the moment?

Eamonn Hobbs: Well, certainly, we have no concerns regarding safety.

Yale Jen: Right.

Eamonn Hobbs: The—and we have—we don't see any reason that the trial would not be allowed to complete as, you know, as we reach it, the September 10th time, it will—the study will be very, very far along. We were at the 75th percentile in early June.

Yale Jen: Right.

Eamonn Hobbs: So, it's unlikely, I think, the DSMB would curtail the trial before we reach the 92 patient enrollment level.

Yale Jen: Okay, great. And, lastly, just wanted to just get a little bit of flavor in terms of some other indications, particularly on the infectious side, that's just mentioned to see whether you—whether there's any other color you may add to it for time being?

Eamonn Hobbs: Well, we're—we are very, very interested in the potential for the system to treat infectious diseases, and where we are in that program is, we are in the preclinical stage and would expect that, assuming that that goes well, that we would be entertaining entering a Phase I or Phase I/II level within a year.

Yale Jen: Can I ask you, lastly, for the neuroendocrine study that, would the investor and purchaser — probably at the end of the year—not too distant future, does additional data come out, or did most of the data has been presented already, and how should we think about this data, part of the new endocrine studies?

Jason Rifkin: That arm of the Phase II study continues to enroll patients, and once that trial is fully enrolled, data will be presented.

Yale Jen: Okay, and would there be sort of top line data first and patient data later on, maybe in some sort of medical conferences, to procure that part of, sort of exposure?

Jason Rifkin: That is correct. That data will be presented at medical conferences as it is completed.

Yale Jen: Okay, great. Thanks a lot, I appreciate it.

Eamonn Hobbs: Thank you, Yale.

Operator: Thank you. Our next question comes from the line of Gabe Hoffman with Accipiter. Please go ahead.

Gabe Hoffman: Hi. Good afternoon, and thank you for taking my question. The first question, just two parts, on your balance sheet, it looks like you've got about, you know, 8.9 million in cash and equivalents and, you know, the burn was about 2.8 million in the quarter on a cash basis. So, you know, two parts, one would be, you know, how long do you expect that cash to last under your current plans, you know, where you get—you know, where you, you know, your sort of minimum comfort level is in terms of, you know, months or quarters of runway, and, you know, finally, if any of the—if you have any warrants or anything—and I apologize for not knowing in advance, I'm new to the story, but if there are any warrants or other things which, you know, the Company has some sort of, you know, call feature on where your stock trades over a certain price for a certain time, that you can, you know, force a conversion and get more cash that way?

Eamonn Hobbs: Well, as far as runway goes, we anticipate that we have enough cash to get us through the next two quarters, and we are still working out the details of the plan to ramp up the operational side of the business. But even with that, having said that, I think we are pretty comfortable that we have enough to get through the remainder of the calendar year. With regard to warrants with call features, I don't believe we have any—do we?

Barbra Keck: I don't think we can force a call.

Eamonn Hobbs: Yes, I don't believe we can force a call on our warrants. But—yes, everyone agrees that we can't.

Gabe Hoffman: Well, okay. Fair enough. And just, and apologize again, I'm relatively new to the story. Just curious, in terms of, if you could, you know, walk through some basic assumptions on powering of your—of your Phase III melanoma study, in other words, what is your assumption for the, you know, number of months of PSS? In the comparator arm, PSS, obviously, being the primary endpoint, what sort of absolute difference—I assume it's in terms of months, are you powered to detect, you know—you know, for example, were powered to detect—you know, 85% powered to detect a, you know, two-month difference or, you know, whatever that may be?

Jason Rifkin: In terms of the hepatic progression-free survival, that's now in line with the FDA with our special protocol assessment. We are shooting for 7.73 months of hepatic progression-free survival versus what's estimated for the best alternative care at four months.

Gabe Hoffman: So, what sort of—so, you're basically shooting—you're basically powered, you know, at some relatively high percentage to detect, you know, roughly a 90%, you know, increase in PSS over comparator?

Jason Rifkin: We're powered at 85% for the 92 patients that we're hoping to enroll in the study.

Gabe Hoffman: To get that sort of 3.7-month PSS difference?

Eamonn Hobbs: That's correct.

Gabe Hoffman: And, okay, that's very helpful. Thank you.

Operator: Thank you. Our next question comes from the line of Larry Haimovitch with HMTC. Please go ahead.

Larry Haimovitch: Good afternoon, Eamonn.

Eamonn Hobbs: Hello, Larry. How are you?

Larry Haimovitch: Good. Congrats on your first conference call.

Eamonn Hobbs: Thank you very much.

Larry Haimovitch: Not first ever, but first at Delcath. I—there—a lot of the questions I had were answered—were answered already, lots of good questions. I just wanted to understand one thing, and that is, you're using—your product is kind of a combination or a hybrid product of a drug and device, and I just was curious about the regulatory path, which agency—which part of the agency do you deal with, and have there been any issues because you're obviously not a pure device, at least not how I understand it.

Eamonn Hobbs: Well, it's—that's an excellent question, and, well, this is a combination product from a regulatory perspective in that there is a device component, which is the

Delcath PHP System, and that requires a PMA. But there's also a necessity to get specific drug labeling that will allow for the drug to be dosed and used with the Delcath PHP System. So, there is a 505 P2 aspect, NDA aspect, to the regulatory path as well. So, from a regulatory perspective, we are a combination product. From a commercial perspective, the way I see the Company progressing is as a device company that is partnered with pharmaceutical partners. The pharmaceutical companies really have a tremendous upside benefit from working with Delcath in that we can take their chemotherapeutic agents that they've already gotten approval for, and add specific labeling that will allow them to increase the efficacy of their drug in patients where it can provide tremendous benefit. And in addition, it's—this is the first device I've ever worked with in my career that actually increased the amount of drug that could be used while increasing efficacy at the same time. Usually, devices do the exact opposite and dramatically reduce the amount of drug that is necessary to reach a therapeutic level. So, there's always been a bit of tension between device companies and pharma companies on those issues. In this one, it's the exact opposite, there's synergy for a win for the pharma company, a win for the device company, and most importantly, there's a win here for the patients who are getting a new treatment alternative that was not available to them before.

Larry Haimovitch: Yes, Eamonn, as you might imagine, the thrust of the question is, is that sometimes we've seen situations where the device side and the drug sides do not see eye to eye and you get into a regulatory nightmare. It sounds from your explanation like you're fine in that regard, and I know you're fairly new to the Company, but what's your thoughts, or what's the thoughts of the others that are there in the room about that? Are you feeling, from what you've seen, very comfortable that there isn't likely to be a turf battle, so to speak, or any other issues that could affect the ultimate approval of the product?

Eamonn Hobbs: Well, I've had that nightmare, that recurring nightmare, exactly, about the FDA. And this is my third combination product that I've been involved with in my career. I seem to be somehow destined to constantly be involved with combination products, but in this particular case, drugs have taken the lead, a very clear lead, and we think that's very favorable in that I've been involved where there wasn't a clear lead in other situations and that definitely led to some difficult situations for the Company, in my prior lives. In this case, it is as clear-cut as it gets. We also benefit from a special protocol assessment, an SPA, and orphan drug status. So, you know, I wouldn't want to tell you that we're all counting our chickens, but we do take some comfort in that we are benefiting from all the bells and whistles you can benefit from going into a very complex combination product, of regulatory approval. So, that's a very long way of saying that I think we're on the right track, and I think the regulatory pathway is as clear as it's ever going to get.

Larry Haimovitch: Yes. Do you have any thoughts or speculation at this point, Eamonn, on whether you would need to go to a panel meeting? This is a unique and relatively new—quite a new concept. Would you expect that a panel meeting would be part of the regulatory path to FDA approval?

Eamonn Hobbs: Well, I have a—I have a little shrine at my house where I burn incense, hoping that we are actually not going to go to panel. But I'm not sure how efficacious the little shrine's going to be.

Larry Haimovitch: How about the lepracon? What about that?

Eamonn Hobbs: Absolutely. The lepracon's holding the incense, actually.

Larry Haimovitch: Okay, good. Fair enough. Okay, thanks very much.

Eamonn Hobbs: Thank you, Larry.

Operator: Thank you. Our next question comes from the line of Bart Blout with Sawtooth Capital Management. Please go ahead.

Bart Blout: Hi. Thank you very much. Two separate questions. Number one, in the event of 18 crossover patients, do you expect that to—what part do you expect that to play in the outcome of your overall results?

Jason Rifkin: The patients that are being treated as crossover patients contribute to our safety and our toxicity data. Now, these patients are treated differently and not part of necessarily that 7.73 first four-month analysis. But the more patients that are treated with the PHP System does answer that safety profile that we will be presenting to the FDA. So, those crossover patients are certainly beneficial to our application, and that's further to the fact that these patients are fortunate, that they show that any patient enrolled in this randomized trial will be able to get the PHP System regardless of what arm they're randomized to if they, in fact, do progress in their livers.

Bart Blout: So, by separating them, you won't, let's say, by being a good human being, you won't hurt your overall results, then, or they'll be indicated as such, right?

Jason Rifkin: These patients should not have any impact on our submission regarding hepatic progression-free survival. If anything, these patients will benefit our application to the FDA.

Bart Blout: Okay, then, the second question is, with respect to money, you want—do you want to license or do you want to raise money in the market?

Eamonn Hobbs: Well, you know, we're considering both of those, and, you know, I think the facts and circumstances are the availability of, you know, one or both of those routes is going to dictate where we'll actually end up. So, by that I mean we can't predict when a strategic partner would come to the table with a potential infusion of capital. But, we are certainly pursuing that with vigor. And our assumptions with regard to the raising money in the capital markets is that we would certainly take into account what we're capable of raising via strategic partnerships. So, but there—you know, we're going to have to play that by ear as we go along. You know—

Bart Blout: The reason why I asked you is it's been a long pregnancy, and typically, in these type of situations, I know the shareholders that have been around a long time would far prefer you to put it elsewhere because it seems like the more loyal you are, the more you get—in other words, the last guy in gets the best deal in the public markets, and the first guy in doesn't get any inheritance to reward besides exhibiting more patience. So, what would be the time period, or what events would have to occur in your mind before there would be some company that would seize the opportunity to license your product and bring in for its revenue?

Eamonn Hobbs: Well, you know, I certainly understand that it would be preferable to our current investors if the Company could finance all of its growth through a means other than the capital markets. Having said that, you know, we are pursuing those means. I wouldn't want to get into too much detail there, as you could well imagine, if they were listening right now, I wouldn't want to discuss any negotiations in any great detail. But what I would say is that we are very serious about attracting and taking on strategic partners in order to facilitate the growth of Delcath. Predicting when those deals come to fruition is very difficult. I have quite a bit of experience with Asian partnerships, and they do take time to put together. The Asians are very thoughtful and very methodical, and they do a very thorough job of due diligence. So, rushing them only makes the process even longer, not shorter. So, we're engaged at the current time and on multiple fronts, and we are pursuing those.

With regard to the growth of your Company, Delcath, the good news is that we are transitioning from being a developmental stage company to an operational one that is looking forward to finally getting to revenues, and those starting, hopefully, mid-2010, in the very near term. And, you know, this is a very positive turn of events for the Company, and even if it does require additional capital, it is going towards an extremely positive long-awaited outcome for the Company.

Bart Blout: So, you're saying that there's somebody signing a licensing agreement, or whatever, it's data dependent?

Eamonn Hobbs: Oh, certainly. The due diligence that potential partners conduct has certainly been picking up, their interest level has picked up significantly because of the progress we've made in the Phase III pivotal trial. And as that trial becomes fully enrolled and completed, it is, you know, it's a—it's a very, very significant asset that is, hopefully, extremely convincing to potential partners. So, you know, the—that is—that is what the Company's all about.

Bart Blout: Yes. And then, lastly, the people that are possibly considering, would a pharma company be—that produced the product be a consideration, or would that not be smart? Like, what is there, just about two people that supply most of the stuff that is the chemo?

Eamonn Hobbs: Well, definitely, our most likely strategic partners are pharmaceutical companies that already are marketing the chemotherapeutic agents that can benefit from the Delcath System. So, the current drug that we're using, melphalen, is sold under a brand name of Alkeran by GlaxoSmithKlein, GSK. The drug recently went generic and is—actually, in June, right—the day before our annual meeting, and is now being also marketed by Vidaza-Zulassung in the United States. So, that's—there are two suppliers in the United States now of melphalen. Outside of the United States, there is a very broad spectrum of manufacturers and marketers of melphalen, including GSK, with the branded Alkeran, and then numerous generic companies. But we're also interested and other strategic partners are interested who have other chemotherapeutic agents that can benefit from the system. So, I wouldn't want to limit it to just melphalen.

Operator: Thank you. Our next question comes from the line of Tony Keller from Raymond James Financial Services. Please go ahead.

Tony Keller: Thank you for the opportunity, but my questions have already been answered. Thank you very much.

Eamonn Hobbs: Thank you.

Operator: Thank you. Our next question comes from the line of Mark Enbody, private investor. Please go ahead.

Mark Enbody: Good afternoon, gentlemen.

Eamonn Hobbs: Good afternoon.

Mark Enbody: I was just wondering, has there been any work on the filters, any new applications, any new filters? I know that we took a stake or bought some stock in one filter company. I'd just like a general update.

Eamonn Hobbs: Really, the filter development program is progressing. We've made tremendous progress in being able to provide the filters presterilized and pre-primed. So, that is a tremendous benefit for the clinicians as far as the ease of use. And that was always in the cards as we move towards commercialization. So, a lot of progress there. We have numerous development programs going on to optimize the filter further, both for the current drugs as well as future potential indications.

Mark Enbody: Well, thank you for taking my call.

Eamonn Hobbs: Our pleasure.

Operator: Thank you. We have a follow-up question from the line of Gabe Hoffman from Accipiter. Please go ahead.

Gabe Hoffman: Hi. Thank you for taking the follow-up question. What is the interval of assessment specified in the protocol to detect PSS? For example, is it every four weeks, every six weeks, every eight weeks, or something else?

Jason Rifkin: It starts, for the Phase III and melanoma trials, the assessments are done every six weeks, eight weeks, and 12 weeks after that. So, a patient is going to be randomized in the trial, and their first set of scans will be six weeks, and they will evaluate hepatic progression-free survival at that point. And then, if a patient does not progress, they will continue getting their treatments on either arm. And then, once they do it, have progressed, at those intervals, they will have the option to cross over.

Gabe Hoffman: And then, after week 12, presumably, it's every four weeks thereafter?

Jason Rifkin: Actually, every eight weeks thereafter.

Gabe Hoffman: Oh, every eight weeks thereafter, okay, great. And I noted from your prior transcript that under the FDA, you need 73 events. Now, with 61 patients that were enrolled at the time of your last call, and you're up to 79 now, if we sort of, you know, went through the, you know, assumptions that you've outlined and things went according to plan, should we be thinking about, essentially, you know, eight months from sort of today, eight to nine months, if you will, like 10 months, as when you'd have enough events and, you know, we'd see the data, or could you help me with how one might think about that time frame, if I should be thinking about it differently?

Eamonn Hobbs: As far as last patient out?

Gabe Hoffman: Well, when you'd actually, you know, have enough events to, you know, issue a press release with the, you know, results?

Jason Rifkin: In terms of thinking about the events first enrollment, I think the best bet is to assume that there will be 92 patients enrollment in this trial, and then the events will be analyzed at that point.

Gabe Hoffman: Right. Right, I mean, obviously, you'd—you know, based on your rate of enrollment, you'd certainly reach full enrollment before hitting, you know, 73 events. But you wouldn't wait until you saw events for all, you know, all 90-some-odd patients to release the data, or would you?

Eamonn Hobbs: You know, I think it's most likely that we would complete the trial and look at the events of all 92 patients before releasing the data. I think that's the most likely scenario. It—and, you know, we estimate that that would put the data released at somewhere in the April timeframe of next year.

Gabe Hoffman: Now, does that—does the powering assumption that you've been kind enough to provide earlier, is that based upon an assumption of 73 events and therefore, if you waited for all 92, you'd have some, what, increased power, or were those figures based on seeing all 92 events?

Eamonn Hobbs: No, we should have—well, depending on how many drop out of the trial, which we have not seen a lot of to date, assuming that we had 92 patients that were active, we should have a higher power, a higher number—

Gabe Hoffman: Sure.

Eamonn Hobbs: Of the total.

Gabe Hoffman: I guess, if you could just help, reconciling to the powering that you've provided, 7.73 versus four, maybe a more clear way to ask the question would be, what is the implied number of events to get that 7.73 at four months, 85% power to detect?

Eamonn Hobbs: Really, the best way probably to answer your questions would be to meet with you either in person—

Gabe Hoffman: Certainly, I'll get in touch with your—with the group you'd mentioned [talk over]—

Eamonn Hobbs: Yes, and we—

Gabe Hoffman: Thank you so much.

Eamonn Hobbs: It would be our pleasure to do that.

Gabe Hoffman: That's great, thanks.

Operator: Thank you. And as a reminder, ladies and gentlemen, if there are any questions—additional questions, please press the star followed by the one at this time, and if you're using speaker equipment, it will be necessary to pick up your handset before making your selection. Once again, if there are any additional questions, please press the star followed by the one at this time. One moment, please, for our next question.

Our next question comes from the line of Steven Rosner with SLD Capital Corporation. Please go ahead.

Steven Rosner: Yes. Eamonn, how are you? I met you at the annual meeting.

Eamonn Hobbs: Oh—I thought [talk over]—

Steven Rosner: I saw, through the slide show, and I saw the other studies that we're going through with the NCI and the one that I saw that we're really progressing along on the Phase II was the pancreatic, that we're kind of—well, we're kind of—we're getting great results, but we're kind of stalled out with needing one or two

more patients. How are we—how are we going to move along with that one since it's a—it's a great field to be in?

- Eamonn Hobbs: Well, the best answer I could give to that question is that we agree that the—it's a very exciting trial and a very compelling trial. And Jason and I have a meeting with the principals at the NCI in a couple of weeks to discuss that very topic. So, we're all very eager to complete that trial, and we're looking for every means to do so in the shortest amount of time.
- Steven Rosner: Yes, because I—if I remember right, the charts were saying that we're extending life, what, between 15 and 18 months on that study?
- Eamonn Hobbs: That's right.
- Jason Rifkin: That study is showing great results, and we will end up completing enrollment in that study.
- Steven Rosner: Do you have a timeframe, do you think, since we only need one or two more patients?
- Eamonn Hobbs: Well, I wish we did, that's what we're—we're going to go meet with the investigators and have an eye-to-eye and figure out whatever we can do to facilitate that. I mean, we're all—everybody's looking forward to finishing that trial because it is—so, obviously, a positive trial.
- Steven Rosner: Yes, the biggest—the biggest trial, I guess, if we win it now, I'm not sure if we have a Phase I in colorectal, do we or do we not? Since that's probably the largest patient group, potential.
- Jason Rifkin: That's—we are currently not enrolling a Phase I trial for colorectal cancer.
- Steven Rosner: Okay. The other question I had is, on your release you put out that you've interviewed 40 more possible patients. Is that—did the 18 come out of those 40, or are these 40 additional ones?
- Eamonn Hobbs: The 18 came out of the 41.
- Jason Rifkin: The 18 crossover patients, you were talking about—?
- Steven Rosner: No, no, no, I'm talking about since April, you've put on—you've put on 18 new patients into the entire study. You've put on, actually, 10 since the annual meeting on July 6—on June 16th, which is almost averaging two, you know, two a week. I'm just trying to figure out, of these 40 new interviews, were they—were those patients, did they come out of those interviews, or are these additional interviews that you've done in the last month or so?

Jason Rifkin: These are—these are patients that have been screened since the last conference call and then since the annual meeting. The patients are continually being screened by the investigators at these centers. So, that's [talk over]—

Steven Rosner: So, it's possible, since we only need 13 more patients, that we probably—we may have seen those 13 potentials already in this group?

Jason Rifkin: That's a very interesting question. In fact, a number of the patients that are screened by these investigators and ruled not eligible are ruled not eligible at that time, in that they have a significant amount of extrahepatic disease, and if that disease can, in fact, be controlled, and then their liver turns out to be the predominant area of disease, then that patient may be eligible at that point.

Steven Rosner: Okay. So, are—what you're saying is, our interviews have gone up substantially with all the—with all the press and everything?

Jason Rifkin: Yes, it's—the press, it's a number of factors, and the trials and momentum has been rebuilding on itself. So, as we move forward, there will be more patients being seen by these investigators and screened for this trial. And the same goes for the Phase II that's enrolling.

Steven Rosner: Mm-hmm.

Jason Rifkin: And I do want to just clarify one comment I made. We are not enrolling a Phase I trial for colorectal metastases, but we are enrolling an arm of the Phase II at the National Cancer Institute for patients suffering from metastatic adenocarcinomas, which can include colorectal metastases.

Steven Rosner: Okay. And so, let me ask you another question about medical devices, if this would be approved, let's say, sometime in the middle of next year, this system, would it be eligible for—to be used for other diseases off label, if the NCI is testing them at that point—time and having good results?

Eamonn Hobbs: Well, when you—when you're asking, “would it be eligible,” the clinicians are free to use devices as they see fit in the practice of medicine. Having said that, we, as device makers, are extremely limited to only marketing devices for their labeled indication. So, we can't market off label use, and—

Steven Rosner: I understand, but you can control everything that they use it for, is what I'm saying?

Eamonn Hobbs: That is the practice of medicine, and it is very typical for physicians to use devices off label as they see fit across all of medicine. So, it—you can read between the lines there [talk over]—

Steven Rosner: Yes, I can read.

Eamonn Hobbs: Yes—

Steven Rosner: And I'm mostly very encouraged that you're going to go out, and I your background is—I've looked at ANGO, they have a lot of institutional ownership—

Eamonn Hobbs: Yes.

Steven Rosner: And that's what we lack at this time, and it's very encouraging that you're going to be going out on the road and talking about Delcath.

Eamonn Hobbs: Absolutely, and certainly, a tremendous amount of focus on telling the Delcath story to institutional investors, yes.

Steven Rosner: Okay, thank you.

Eamonn Hobbs: Thank you.

Operator: Thank you, and at this time, I'm showing no further questions in the queue. Please continue.

Eamonn Hobbs: Well, thank you, everyone. We are very encouraged about our recent progress, and we'll plan to update you again in October. Thank you for your interest and your support. Have a good evening, and all the best to each one of you. Good night.

Operator: Ladies and gentlemen, that does conclude our conference for today. If you'd like to listen to a replay of today's conference, it will be available until August 3rd of 2009 at midnight. You may access the replay system at any time by dialing 303-590-3030 or 1-800-406-7325 with the access code of 4117854, pound. Thank you for your participation, and at this time, you may now disconnect.

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