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): **June 15, 2010**

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-16133	06-1245881
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

810 Seventh Avenue, Suite 3505, New York, New York, 10019
(Address of principal executive offices, including zip code)

(212) 489-2100
(Registrant's telephone number, including area code)

NONE
(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

[ ] 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 7.01. Regulation FD Disclosure.

On June 15, 2010, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss recent corporate developments. A copy of the transcript of the conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The information disclosed under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

Exhibit No.	Description
99.1	Delcath Systems, Inc. Conference Call Transcript

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.

DELCATH SYSTEMS, INC.

Dated: June 17, 2010

By: /s/ Peter Graham
Name: Peter Graham
Title: Executive Vice President & General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Delcath Systems, Inc. Conference Call Transcript

DELCATH SYSTEMS INC., # 4317816
DELCATH SYSTEMS INC. - UPDATE CONFERENCE CALL
June 15, 2010, 4:30 PM ET
Chairperson: Doug Sherk (Mgmt.)

Operator: Good day, ladies and gentlemen. Thank you for standing by. Welcome to today's Delcath Systems Update Conference Call. During today's presentation all participants will be in a listen-only mode. Following the presentation the conference will be open for questions. If you do have a question, please press the star, followed by the one on your touch tone phone. Please press star, zero for operator assistance at any time. For participants on a speaker phone, you'll need to pick up the handset before making a selection. This conference is being recorded today, Tuesday, June 15th of 2010.

I'd now like to turn the conference over to Doug Sherk with EVC Group. Please go ahead, sir.

Doug Sherk: Thank you, Operator and good afternoon, everyone. Thank you for joining us today for this update on the recent progress at Delcath Systems. A replay of the conference call will be available beginning approximately one hour after the call's conclusion, and will be available for seven days. The Operator will provide replay details at the conclusion of today's call. This 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 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 and submit the new drug application to the FDA, acceptance by the FDA of our clinical trial data and NDA application, the company's ability to secure regulatory approval of current or future drug delivery systems in the United States and foreign markets, actions by regulatory authorities, changes in the healthcare environment, i ncluding reimbursement, and overall economic conditions and uncertainties in the 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 filings with the Securities and Exchange Commission, including the Form 10-K for the fiscal year ended December 31, 2009, which was filed on February 26th, 2010. 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.

In addition, during today's call, we realize that many of you may have questions, and in order to provide everyone with the opportunity to ask questions, we will be limiting each participant to two questions and encourage you to request to ask additional questions by re-queuing. Given management's schedule, we have allowed one hour for today's call.

Now, I'd like to turn the call over to Eamonn Hobbs, President and Chief Executive Officer of Delcath Systems.

Eamonn P. Hobbs: Thanks, Doug, and good afternoon, everyone. Joining me this afternoon are Dave McDonald, our CFO; Kris Kandarpa, our Chief Medical Officer and Executive Vice President of Research and Development; and Drs. Sanjiv Agarwala; Eric Whitman and Jonathan Zager. Dr. Sanjiv Agarwala is Chief of Medical Oncology, St. Luke's Health System in Bethlehem, Pennsylvania. Dr. Whitman is Director of the Atlantic Melanoma Center and Medical Director of the Office of Grants and Research of Atlantic Health, both in Morristown, New Jersey. Dr. Zager is an Assistant Member of Cutaneous Oncology and Sarcoma Program at Moffitt Cancer Center in Tampa, Florida. We deeply appreciate the doctors taking time out of their very busy schedules on such short notice to participate in today's call.

Our agenda today is to brief you on the Phase 3 trial results presented at ASCO and provide a sense of how the oncology community here in the United States is reacting to those results. In addition, we want to openly address the questions raised on a variety of subjects during the past week, including the status of our special protocol assessment (or SPA) with the FDA and market opportunities we believe Delcath Chemosaturation System will address assuming FDA approval of our new drug application to market in the United States. Finally, we'll address questions that you may have today.

Let's begin with Kris Kandarpa, our Chief Medical Officer, to review the key results from the study.

Kris Kandarpa: Thank you, Eamonn. The Phase 3 trial was conducted under special protocol assessment (or SPA) which was developed in close cooperation with the FDA's Office of Oncology Drug Products. This SPA was deemed acceptable by the FDA in a letter dated February the 9th, 2006. The trial was designed to enroll 92 patients with ocular or cutaneous melanoma that had metastasized to the liver. Patients who were randomized one to one to either the chemotherapy by percutaneous hepatic perfusion (or PHP) arm by the control defined as best alternative care (or BAC). Patients in

the chemosaturation via PHP with Melphalan arm were treated every four weeks and responders could receive up to six rounds of treatment. Patients in the BAC arm received treatment they and their physicians had agreed upon. For most, the BAC arm included chemotherapy, chemoembolization and a variety of focal, image guided treatments. A few received just supportive care. To the extent BAC patients did not respond to their therapy, they were allowed to cross-over and receive Chemosaturation therapy via PHP provided they still met the trial's original eligibility criteria. The majority of BAC patients did in fact cross-over to receive chemosaturation therapy.

The primary endpoint of the trial, in accordance with the SPA, was to show a statistically significant difference in hepatic progression free survival or (HPFS); significance being defined at a p value of less than 0.05. For those not familiar with the endpoint of progression free survival, a Journal of the National Cancer Institute publication earlier this year on FDA's Office of Oncology Drug Product Approvals between 2005 and 2007, reported that progression free survival was a common primary endpoint for studies that resulted in drug approvals. In fact, according to this report, nearly 80% of approvals were based on studies that did not use overall survival as a primary endpoint.

In our study, in addition to the overall survival there were a variety of secondary trial endpoints including hepatic objective response, duration of hepatic response, overall response and duration of overall response. The statistical analysis plan also allowed for sub-group analyses. Our study showed that the primary endpoint results for chemosaturation via PHP far exceeded those of the control arm. At ASCO, the investigators reported median hepatic progression free survival (or HPFS) for the treatment arm of 245 days, which is 5x the median hepatic progression free survival of 49 days for the BAC control group. It is notable that the 95% confidence intervals were widely separated with no overlap whatsoever and that the p value was 0.001 indicating a very strong significance t o the magnitude of this difference between the groups.

In addition, the hazard ratio was 0.301, meaning the control group had a greater than 3x more likely risk of hepatic tumor progression or death. 90% of the patients in our study had ocular melanoma and 10% had cutaneous melanoma, with no significant difference in the results between the two groups. The SPA calls for an equal distribution of patients in each treatment arm but did not require subset analysis between cutaneous and ocular patients. It is important to note that because of the non-selective mechanism of action of Melphalan, which is an alkylating agent, response to treatment is independent of the site of cell origin. This is consistent with historical literature as well. Overall progression free survival was reported as 186 days for the PHP arm versus 46 days for the BAC arm with a p value of 0.001, hepatic objective response rate with 34.1% of

PHP versus 2% for BAC with a p value of 0.001. However, when BAC patients cross-over to PHP, their progression free survival rose to 22%.

As I'd mentioned previously, the majority of the BAC patients crossed-over and obtained a similar response from the chemosaturation therapy. This was raised as an issue by the discussant who was supposed to provide an objective review of Dr. Pingpank's ASCO presentation. However, cross-over was designed into the trial as per SPA requirements and guidance and for ethical reasons with prior realizations that the overall survival results could be confounded by the cross-over provision of the trial. Therefore, as expected, because of the higher level of cross-over, the intent to treat analysis showed no difference in the secondary endpoints of overall survival between the two arms. This is because the benefit accrued to BAC patients after they crossed over to PHP was still credited to the treatment arm that they started in. It should be noted that although the intent to treat analysis showed no difference between the two study arms, they both nevertheless had a far higher overall survival of around 300 days compared with historical reports and were also significantly higher than the overall survival of 124 days in the non-cross-over BAC patients. Of note, previous overall survival data referred to by Dr. Pingpank's critic at ASCO were from older studies that used different inclusion/exclusion, treatment, and evaluation criteria. More importantly, they were from small uncontrolled non-randomized single center studies that are academically categorized as providing the lowest level of medical evidence and thus rendering them strictly non-comparable to a modern prospective randomized control multicenter study such as ours.

Finally, the safety profile was expected and in line with current FDA approved labeling for the IV administration of Melphalan, and the Phase 1 chemosaturation PHP studies that we conducted earlier. There were three treatment related deaths in the PHP arm, two were attributed to neutropenic sepsis, resulting from the bone marrow suppressive action of Melphalan; one was due to excessively large tumor burden of over 95% and an inadequate residual viable liver that ultimately led to hepatal renal syndrome. I would like to add that Delcath intends to institute a risk evaluation and management system when the product becomes commercially available.

At this point, I'd like to ask the doctors on the line for the interpretation of their results and their thoughts on what has happened so far. Let's start with Dr. Sanjiv Agarwala. Sanjiv?

Dr. Sanjiv Agarwala: Yes, thank you. So, I was a co- investigator on this trial and as you saw from the ASCO presentation, this was by all definitions a positive trial for its primary and secondary endpoints. This is very tough because they used metastatic melanoma, it involves a liver with a high frequency, particularly in ocular melanoma but also in cutaneous melanoma, and

unfortunately, current therapeutic options, even from the recent ASCO meeting and some new results that you've seen with other drugs with patients with hepatic metastasis that results at poor. There is no question that [inaudible] administration of Melphalan by this technique there is a high response rate and improved progression free survival in the liver with this agent, which in my opinion does provide certainly a therapeutic option for these patients that can be quite effective. In my experience with this therapy, it has been well tolerated recently with the side effects that you would expect. Nothing untoward that was seen on this randomized trial. The strongest piece of data that I can take home from this clinical trial was the fact that because of the cross-over design, and that wa s specifically those into the protocol as you'd heard, patients who did not respond to other care or best alternate care, were allowed to cross-over if they met the original eligibility criteria and a considerable proportion of those patients responded. So to me that is those patients acting as their own controls and proved the point that whatever else we had available at that time, and really what we have even available today, does not work in terms of liver metastasis. But, indeed, if those patients are able to get this treatment there is a response and an improvement in progression free survival for those patients.

Kris Kandarpa: Thank you, Sanjiv. Appreciate your comments. Now, Dr. Eric Whitman. Eric?

Dr. Eric Whitman: Thanks, Kris. And thanks for inviting me to participate today. I agree with Sanjiv that to me the simplest take-home message from this trial is the magnitude of the clinical response. We're not talking about going from four months to six months or six months to ten months, we're talking about going from a couple of months to seven months. You know, triple, and I think its important, as Sanjiv said, that even the patients who initially were randomized to BAC if they were able to cross-over if they still mete the entry criteria, still benefited, which is why, as you pointed out, the survival curves overlapped. So I think this is a really exciting new treatment and I look forward to it being approved. I think it's doable in lots of different centers. We are n ot a university center and we, I think, did it quite well and safely and I think that will translate across the country and really across the world. So, thank you again for allowing me to participate.

Kris Kandarpa: Thank you, Eric. And yes, your center did very well indeed. Now, Dr. Jonathan Zager. Jonathan, comments, please?

Dr. Jonathan Zager: Yes. I think both the other doctors summarized it very nicely and just to reiterate, it wasn't meant to be a survival trial and actually you would expect the survival to be similar on both groups, allowing those best alternative care patients to cross-over to the PHP arm. If it still was different, you would think that there may be a problem. You know, in my

opinion, that the most convincing data is that overall -- I mean obviously, a 5x increase in progression free survival is a huge triumph in metastatic melanoma to the liver, which is just almost impossible to treat systemically. But then when you look at the overall survival of the best alternative care patients who were allowed to -- who could cross-over, you know, that's just a, to me, it's a great Kaplan-Meier curve, but really shows that you're able to take patients who have a bad problem, they have to progress at least 20% in their liver to be called a progressor on the trial, then they cross-over to a therapy which is able to salvage them and significantly impact their overall survival. I just think that that shows you right there how powerful this treatment is and how well it can be used in these patien ts, affecting both progression free and overall survival indirectly like that.

Kris Kandarpa: Thank you, Jonathan. I'd just like to iterate that you've heard both from medical and surgical oncologists. But before I turn the call back to Eamonn, I'd like to update you briefly on the status of our Phase 2 trial that is underway at the National Cancer Institute.

We're currently in the data analysis phase in preparing for our publication strategy. We hope to see the study published by the end of this year. Eamonn?

Eamonn P. Hobbs: Thank you, Kris, and other esteemed doctors. At this point, let me briefly address the key remaining questions we've received during the past ten days.

First, is progression free survival primary endpoint enough for potential FDA approval? The answer to this question is yes. First, the FDA provided input in the development of our SPA, with hepatic progression free survival being the primary endpoint. Second, in the same 2005 to 2007 retrospective analysis that Kris mentioned previously, progression free survival was the primary endpoint for 11 of 53 oncology drugs approved during this time frame.

A second question concerns what indication will the FDA potentially approve? At our March 9th pre-NDA meeting with the FDA, Phase 3 and other data was presented and deemed acceptable by the FDA for our NDA application for the indication of metastatic melanoma to the liver, ocular or cutaneous. It is important to note that there are no treatment result differences between ocular and cutaneous melanoma in the study and there is no requirement under our SPA for an enrollment minimum of either ocular or cutaneous melanoma. As Dr. Kandarpa mentioned during his comments, both tumor types when present in the liver responded in the same manner when treated with Melphalan and this scenario is consistent with historical literature

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Another question is the market opportunity for chemosaturation therapy via PHP. We are pursuing labeling for both cutaneous melanoma and ocular melanoma that have metastasized to the liver. According to a 2009 report of the American Cancer Society, in the United States, cutaneous melanoma is reported in approximately 68,720 patients, and ocular melanoma is reported in approximately 2,350 patients. Literature suggest that liver metastasis predominate in about 20% of the cutaneous patients and about 75% of the ocular patients. Although patients in the treatment arm of the Phase 3 trial received an average of three chemosaturation via PHP treatments, we have elected to use in our potential market modeling a more conservative forecast of 2.5 treatments per patient. Assuming an aver age selling price to Delcath of approximately $20,000, the annual on-label market opportunity in the US alone would be approximately $775 million. In addition, it is important to note that less than 10% of the global liver cases are here in the United States. Based on conversations with physicians, we believe that chemosaturation via PHP will be used off-label for certain patients with a variety of liver cancers, including HCC Neuroendocrine Mets and colorectal metastasis. Based on the $20,000 per procedure average selling price and the 2.5 average number of procedures per patient, we believe that this could result in an overall and off-label US market opportunity of approximately $6.8 billion. Next week, as part of our strategic planning process, we'll be focusing our attention on the development of trials for some of these other indications based on the strong data that was presented at ASCO.

Finally, there is the question of our need to raise capital to fund operations. With that, I'd like to turn the call over to our Chief Financial Officer, Dave McDonald.

Dave McDonald: Thanks, Eamonn. Last Friday when we announced the scheduling of the call, we also provided an update on the financial situation. We've certainly said in the past that we would like to raise additional capital. We filed a shelf registration earlier this year. The company's always evaluating market conditions to determine the best time to raise that capital. However, given the current conditions, it makes no sense to us to access the capital markets at this point, nor do we need to. Our cash position at May 31 was approximately $29.6 million, and the burn rate over the last six months was approximately $1.8 million a month. Clearly, as we continue to ramp up we anticipate increasing the burn rate to north of $2 million per month. However, even giv en all this, we believe we've got 12 months of cash on hand with which to execute our plans. In addition, we continue to negotiate with potential international partners. Those talks have increased subsequent to the ASCO presentation, and we'll report on any developments that may occur.

With that brief update, I'd like to turn the call back over to Eamonn.

Eamonn P. Hobbs: Thanks, Dave. Operator, we're ready for questions.

Operator: Thank you, sir. 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 phone. If you would like to withdraw that question, please press the star followed by the two. And if you are on a speaker phone, you'll need to pick up the handset before making your selection. Please ask one question and one follow-up and requeue for additional questions. One moment please.

And our first question comes from the line of Matt Pommer with Roth Capital Partners. Please go ahead.

Matt Pommer: Good afternoon, everyone. Thank you for taking the questions and holding this call.

Eamonn P. Hobbs: Hi, Matt. How are you?

Matt Pommer: Good, good. First of all, Eamonn, thank you for discussing the portion of ocular and cutaneous patients as it relates to the potential labeling. I was wondering if you could give us a little bit more specifics. So the FDA actually reviewed the safety and efficacy data, the Phase 3 trial in that March 9th meeting, is that correct?

Eamonn P. Hobbs: That's correct.

Matt Pommer: And they deemed it -- they thought it was appropriate and to move forward in that with also the expanded use protocol incorporated with that data?

Eamonn P. Hobbs: There were separate data points; the extended use protocol was filed earlier with the data from the Phase 3 trial, so it was interim data. But at the March 9th meeting they saw the full data set and they deemed that the application was complete enough to allow for the application to be submitted. And certainly, if the -- the whole purpose of a pre-NDA meeting is for the FDA to point out any glaring insufficiencies so that they don't waste their time reviewing something that has no chance of getting approved. So we came out of that meeting -- actually our first question to the FDA in our pre-NDA meeting was, is the submission and data we've presented sufficient for application and they gave us a one word answer "yes".

Matt Pommer: That's helpful. Thank you. And secondly, there were a number of grade 3/4 events in the treatment arm, were they characteristic of the approved labeling of Melphalan? And secondly on that, could you remind of the specifics of the six non-responders? I believe there were six in the treatment arm of the trial. Thanks.

Eamonn P. Hobbs: Actually, you know, we could ask the doctors to respond to that if they're familiar; they're very familiar with the data. Sanjiv, do you want to take a shot at it?

Dr. Sanjiv Agarwala: Well, let me take the first part of that, which was to do with, you know, Melphalan and its side effects. Melphalan is an isolating agent, as pointed out, and indeed on this trial, and even the previous Phase 2 and Phase 1 work from Dr. Pingpank at the MCI [ph], you know, Melphalan has the usual neutropenic and [unintelligible] side effects in accordance with its effectiveness to the chemotherapeutic, so nothing on this trial that was with that regard was any different. Perhaps I can let either Eric or Jonathan talk about the other part of that question.

Matt Pommer: Sure.

Eamonn P. Hobbs: Eric or Jonathan, do you have any comments on this?

Dr. Jonathan Zager: You know, I don't -- I'm not familiar with the characteristics of the non-responders on the treatment arm. I don't know if Eric is familiar with those patients specifically.

Dr. Eric Whitman: No, I think, Kris, you're going to have to respond to that because I don't think Jonathan nor I know the patient by patient specifics.

Kris Kandarpa: Sure. Well, in fact, as I'd stated in earlier, there, what we found was completely in line with the IV administration of Melphalan labeling that it's approved for right now. And we found no consistencies with either that or the prior Phase 1 trial that Dr. Pingpank led.

Matt Pommer: Okay, thank you guys for taking the questions.

Operator: Thank you. Our next question comes from the line of Greg Wade with Wedbush. Please go ahead.

Greg Wade: Thanks for taking my question. Dr. Kandarpa, with respect to the effect progression of liver has on these patients, have you done any analyses that indicate what that progression ends up doing to patients whether, typically they progress in the liver and then die? Is liver progression actually predictive of the survival outcome? Thanks

Kris Kandarpa: So, you're asking if hepatic progression free survival is -- can be a surrogate for overall survival?

Greg Wade: Yes.

Kris Kandarpa: Well, you know, we're actually looking into that. Our indications of preliminary analysis and subgroup analysis seem to favor that and so we will definitely doing our publication be speaking to it. And if, again, if any of the docs want to speak up they're welcome to. They don't have to necessarily respond to this.

Dr. Sanjiv Agarwala: Well, you know, if I could jump in and -- I think part of the question had to do with, I believe, interpreting this as the clinical meaningfulness of responding in the liver as well, and there is no question that melanoma still would remain an incurable disease for a long time in many patients, in most patients. And absolutely, yes, if patients have predominant liver disease and they respond in their liver, they have a benefit. I saw that in this trial I've seen that whenever I've been able to have patients that respond to liver which is not that often, unfortunately, there is no question that liver involvement is symptomatic in many patients, it causes of course increase in liver enzymes and clinical effects that can be reversed by treatment and even if it's not curative there is certainly a clinical meaningf ulness that patients will live longer on an individual basis if they respond to the liver.

Greg Wade: And if I just might follow-up, for patients who unfortunately are progressing in the liver and treatment of it doesn't seem to be having any impact, I mean is there any more intervention that's generally given to these patients or are they generally counseled to pursue a more palliative course?

Dr. Sanjiv Agarwala: Well often when the liver involvement is very extensive and, you know, if it's not -- if whatever you're using is not responding or the patients are not progressing. For example, if somebody on this particular treatment were to respond initially and then, say, six or twelve months later progress, that often it's indicative of other organ involvement as well and that kind of goes along with the whole disease progressing at other areas and then the demise of the patient. So, that sort of does go hand in hand and until you have -- until we have something that actually works in the liver, that's just was the way it was. Whenever we see metastatic melanoma to the liver, in fact we classify it as M1C, which is the worst category of metastatic melanoma, and most of those patients have an elevated LDH as we ll, which is a poor prognostic marker. So, overall, it's a bad thing to have liver metastasis.

Greg Wade: Thanks for taking my question.

Eamonn P. Hobbs: Thank you, Sanjiv.

Operator: Thank you. And our next question comes from the line of Jason Mills of Canaccord. Please go ahead.

Jason Mills: Great. Thanks, guys, for taking, doing this call and taking the questions. So, Eamonn, I don't know if you will allow this to go through to the doctor, if you want to take this. But I'm just wondering, two questions. First on the screening process for these patients, the referral channel in general and what you fores -- what the doctors foresee going forward in terms of getting access to both the on-label and off-label patients, whether or not they expect that to increase dramatically with these results? How much awareness will be there or grow because of these results? How quickly that'll disseminate, etcetera? And the second part of the question is, when you think about off-label use from your perspective, doctors, what, how should we think about your ab ility to get those patients covered under reimbursement? Is it compassionate use? Is it -- do you expect to see or have you seen any issues with getting reimbursement for those patients? Those are my two questions. Thank you very much.

Dr. Eric Whitman: I'm happy to answer, Eamonn.

Eamonn P. Hobbs: Yes, go right ahead, please.

Dr. Eric Whitman: Eric Whitman. The referral process for us on this trial, there were a lot of people that found us because they wanted to be on the trial. One of the things you have to realize about metastatic melanoma patients both ocular cutaneous is that they know they're in a very bad situation, it's very easy for them to find the data that the average survival is under a year, even as Sanjiv alluded to, with the newest and greatest results ever last week at ASCO. So they're looking for something, and ocular melanoma even more, because there's not many trials and there's not a lot of hope for them. So the referral process works quite well from that perspective. I think going forward it's important for us to work with medical oncology colleagues in prior practice.

I think the second question is really the off-label use, and the only thing I'll say about that is, although I'm not doing [ph] -- this is an inpatient procedure and the billing, particularly for off-label use or on-label, use is much different than what you're used to and what you're asking -- referring to in terms of outpatient chemotherapy. The inpatient billing is through DRGs not through J-codes and DRGs are kind of diagnosis independent, so I'm not sure that it's really the same question because when you bill for an inpatient procedure you're not billing for melanoma or colon cancer, you're billing for cancer procedure with chemotherapy for the liver.

Jason Mills: Got it. So really we'll be -- the growth and the use of this procedure will be dominated more by the physician's belief [ph], in the data belief and the procedure itself as opposed to an FDA scrutinizing or governing the utilization of the procedure via the labeling?

Dr. Eric Whitman: Yes, I think that's a hypothetical statement. I mean I just don't know how that'll work, but I do know that it's substantially and completely different than outpatient chemotherapy off-label use. It's just...

Jason Mills: Thank you very much.

Dr. Eric Whitman: ... not the same thing.

Dr. Sanjiv Agarwala: You know, I'd like to add a comment. I think that as the data gets more publicized and more community as well as academic medical oncologists and surgical oncologists see the data and learn about the data, this will be, the procedure will be more widely offered. On the same note, I have almost a patient a day email me with either melanoma or various other histologies, metastatic to the liver who has failed first, second, third line systemic therapies, asking if we could perform the percutaneous hepatic perfusion on them. And I think that not only will the patients bring it up to their medical oncologist but the patients will seek out the treatment as well. In this day and age, I mean patients that have access to the Internet, I think that almost every patient does their due diligence on t reatments that are out there, especially when their disease starts to get advanced and they're going to be a driving force as well requesting that they are referred to people who perform the procedures, obviously when appropriate.

Jason Mills: Thank you.

Eamonn P. Hobbs: This is Eamonn. I would just add to that. You know, with regards to off-label reimbursement, you know, my experience with reimbursement on a case-by-case basis, is it's data driven, and if we look at the data set that we're working with right now, of course we have the on-label data, but then we have a multiarm Phase 2 trial going on at the NCI, which hopefully will get published this year, the most advanced arm of that is neuroendocrine tumors. So, we'll be taking that data and evaluating its usefulness from a reimbursement perspective but also from an additional indication perspective in additional clinical trials that we're going to pursue because clearly that Phase 2 is, and the Phase 3 have convinced us that the technology has tremendous broad based application in a number of different diseases in the liver.

Jason Mills: Great. Thanks.

Operator: Thank you. And our next question comes from the line of Gabe Hoffman with Accipiter Capital Management. Please go ahead.

Craig Yeshion: Hi, guys. It's actually Craig Yeshion for Gabe. Thank you for taking the questions. I'll just say off my two questions and then I'll sit back and let you answer. The first question, just if you could help me understand how technically this worked out. Hepatic progression free survival was about

245 days in the study, yet the overall progression free survival, which should incorporate hepatic progression free survival as one of the potential sources of progression, was actually less at 186 days. So how does that actually happen? That's question one. And then question two, related to the data presented at ASCO, you presented the investigators data, which was a little less rigorous than what you'd presented in your press release on April 21st, which was the blinded independent core lab data, as a result the HPFS went from 214 days originally to 245 days, and the BAC arm actually got worse, from 70 days in the blinded assessment down to 49 days in the investigators assessment. So if you can just let us know if that blinded data changed at all from the initial data you'd presented an d what that data might have been?

Eamonn P. Hobbs: Well, to address the blinded versus the investigators data, Dr. Pingpank presented the investigator data set, which is not unusual in an academic conference such as ASCO. We, as a company, are of course very interested in the core lab blinded data that we'll be submitting to the FDA in addition to investigator data, which is a validation. And there are no -- the blinded core lab data had a p value that was the same as the study, and although the numbers changed slightly, because this is a median analysis and with patients going one way or the other and one of the groups can and did represent the difference between the two data sets. Because this was a resist [ph] criteria, whether a lesion was measured to be 19 or 20%, is the hairline that can determine which group they went in. That's wh at constitutes any differences. We deem those differences between the core lab data and the investigator data to be immaterial with regards to the successful nature of the trial. Whether it's a 3x increase in HPFS or a 5x increase, what's more important is the p value of 0.001 in both data sets and if you take a patient and move them one way or the other, and that accounted for that.

With regards to the first part of your question, maybe, you could restate it and the physicians could tackle that.

Craig Yeshion: Sure. So just to re-state. The hepatic progression free survival was 245 days as presented at ASCO, whereas the overall progression free survival was actually less at 186 days, and overall progression free survival would basically be a progression anywhere in the body, not just hepatic, so if you're incorporating hepatic in conjunction with potentially other sources of progression, the numbers should be, if nothing else, equal or higher. I don't understand how it could possibly be lower than the 245 days.

[Talk over].

Dr. Jonathan Zager: I can answer that question. I can take a stab at it. When I look at those numbers, you can think that some patients who receive percutaneous hepatic perfusions or systemic therapy may have progressed in an isolated

subcutaneous lesion that count as overall progression free survival but that is easily resected. Whereas the bulky disease and the life threatening disease is still in the liver they go on to continue their systemic or percutaneous hepatic perfusion treatment arms, if that disease can be resected in the time point in between two treatments. I think that probably will account for some of the data of overall progression free survival.

Craig Yeshion: I'm not sure if I'm following that because whether it's a cutaneous progression, lung progression or brain progression or liver progression, they all count equally the same.

Dr. Jonathan Zager: That's correct, and that's why the overall progression free survival is less than hepatic progression free, so if your patient A and you had a percutaneous hepatic perfusion and at week four you point out to me that you have a little nodule in your thigh, and I biopsy that and it's melanoma, you are now, you have overall progressed, not hepatic progressed, but overall progressed. I can excise that, make that go away and continue to treat your life threatening disease at a four to eight week interval with your next hepatic profusion. As long as you're not progressing in your liver or progressing systemically that based on our clinical decisions, either change that systemic therapy or go away from percutaneous hepatic perfusion to some other therapy, is necessary, then you would continue on with your same treatm ent arm.

Craig Yeshion: Okay, I got 'ya. Thanks.

Dr. Jonathan Zager: Does that make sense to the other...

Speaker: That makes -- yes, that [unintelligible].

Operator: Thank you. And our next question comes from the line of Fred Graham [ph] with Admiral [ph] Capital Management. Please go ahead.

Fred Graham: Yes, my question is regarding the last part of the call when you spoke briefly about market conditions not being acceptable from the company's perspective when it comes to tapping the secondary markets for raising capital. I guess it's a two-part question. The first is, is there a stock [ph] price which you, or range in which you would be interested in raising capital through the secondary market? Would you prefer to do it with debt if possible or a convertible bond, preferred etcetera? And, if you choose not to use the capital markets, can you discuss more in detail what a partnership would look like? In other words, would it be for the upside in just the ocular and cutaneous indications or would it be for off-label and additional indications in the United States? I f you could just expand on that please?

Dave McDonald: Sure. This is Dave. And we'd never commented on timing or certainly the price levels or what have you, but clearly we feel right now it's not the right time to address the capital markets. What we've said historically in terms of raising capital, as we negotiate with these strategic partners, we've certainly been talking with partners in Asia, those are primarily distribution deals. We've also started talking with partners in the US and Europe with respect to other indications. So I think it could be all of the above.

Eamonn P. Hobbs: And this is Eamonn. I would add, you know, in describing the kind of strategic partnership we're looking for, which includes a distribution arm in Asian partners, we should keep in mind that the potential Asian partners are really far more interested in primary liver cancer than they are in melanoma mets because of the tremendous impact on their societies of primary liver cancer compared to the United States. So, when we're talking about a partnership, an integral part of that is the development of the clinical programs to get approval in China, Korea, Taiwan, Japan, etcetera, for the chemosaturation PHP system for primary liver cancer as well as other metastatic diseases to the liver, and, which are much, much bigger markets than melanoma.

Fred Graham: Okay, great. I appreciate you taking the questions.

Eamonn P. Hobbs: Thank you.

Operator: Thank you. Ladies and gentlemen, if there are any additional questions, please press the star, followed by the one at this time. As a reminder, if you're on a speaker phone, you'll need to pick up the handset before pressing star one. One moment please.

Once again, ladies and gentlemen, if you'd like to ask a question, please press the star, followed by the one at this time. As a reminder, if you're on a speaker phone, you'll need to pick up the handset before pressing star one.

And our next question comes from the line of Mayank Gandhi with Cowen & Co. Please go ahead.

Mayank Gandhi: Good evening, guys. Thanks for taking my question. I have two questions. First, Eamonn, you know, international option [ph] could be fairly significant, so can you just tell us, clarify, where are we in terms of the CE [ph] approval process and what exactly is required by the company to get that approval?

Eamonn P. Hobbs: Well the current status is we are expecting to, a CE approval mid 2011, and that would be for the device side of the chemosaturation PHP system. The European system differs from the United States system with regards

to combination products in that there is a combination product pathway that we are on with FDA, where the FDA has decided that the drug and the apparatus are going to be regulated solely as a drug on the drug pathway. In Europe, there is no such thing as a combination product pathway and there is a distinct drug and device approval. We are filing as a Class 2(b) [correction Class 3] device for our device component of the system. We are applying for orphan drug designation on the drug side, and we would expect device approval mid 2011, which would include a full quality system audit of our Queensbury manufacturing facility as well as a full product dossier review on the device side.

Mayank Gandhi: Okay. So just to clarify, so you're not required to produce [ph] any additional data, correct?

Eamonn P. Hobbs: We don't believe that we would. For a Class 2(b) device, there is no requirement for a demonstration of clinical efficacy; you can use literature. And we think our Phase 3 trial is, and plus Phase 2 multiple other trials, Phase 1 and Phase 2, trials, we believe we have far more than we need from a dossier perspective.

Mayank Gandhi: Okay, that's helpful. And then one follow-up question for the esteemed panel. More in terms of just the, you know, patient selection, two part question. First, you know, given the primary endpoint, how clinically meaningful is hepatic progression free survival? And then, second question is, how do you think about seeding [ph] patients that have disease in other organs?

Dr. Jonathan Zager: So, I can -- I'll start by answering your second question. If your life threatening burden of disease in the liver, no systemic therapy is going to help that. So my plan would be to, and this would be patients that have disease outside the liver, I would go ahead with using that percutaneous hepatic perfusion to get the liver disease under control. Once that liver disease gets under control, continue on with maintenance systemic chemotherapy to try to treat the extra hepatic disease as well as continued treating now [ph], hopefully much less burdensome hepatic disease. That would be for the patients referred to me with both overwhelming liver disease and extra hepatic disease, that would be my plan to treat them in conjunction with the medical oncologist.

Dr. Sanjiv Agarwala: And I can sort of jump in here as the medical oncologist on this panel. There's no question that, you know, we consider cancer in general, melanoma, in particular, to be a systemic disease. There's no question about that and we all understand that we can't ignore extra liver disease, but as has been pointed out by others, the liver part of this is a major issue, both in terms of the fact that its involved [ph] frequently, and also tends to be almost, at least in cutaneous melanoma, one of the most resistant places to have disease which is not responding to other modalities. And this has

been seen in other diseases as well, like colorectal and so on. So even as a medical oncologist, to think systemically all the time, there is no doubt that there are patients who I would like to see what I would consider to be a medical debugging [ph] of the liver that will allow me to then give more effective general systemic therapy that could help other areas as well because the liver is the limiting factor in most of these patients.

Mayank Gandhi: Okay, that's helpful. Thank you.

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

Larry Haimovitch: Good afternoon. Eamonn, congrats and all with the progress.

Eamonn P. Hobbs: Thank you, Larry. How are you?

Larry Haimovitch: I'm doing great. How are you?

Eamonn P. Hobbs: I'm very well, thank you.

Larry Haimovitch: Terrific. I think the question was answered, but let me just rephrase it. I can't remember when it was, maybe a year ago, I think it was your first conference call, you and I had dialogued about the drug device conundrum, it sounds like that's all been cleared up now and the FDA is going to regulate it as one device so you don't have to worry about the different divisions and stuff like that, did I understand that correctly?

Eamonn P. Hobbs: Yes, you did. At our March 9th pre-NDA meeting, because we, as you remember correctly, we had both a concurrent ND -- IND and a IDE pathway to pursue ultimately an NDA and PMA for the drug and the device. At our pre-NDA meeting, the agency called in both drug and device side and also the Office of Combination Products (the OCP), which is the determining body of whether combination products will be regulated primarily or solely as a device, as a drug or both. And the agency came down very strongly on a preference to regulate the Delcath technology solely as a drug, where the drug and the delivery apparatus and filtering system would be packaged together and mated [ph] together so that the variables would be minimized and the regulatory pathway would be very straightforward. So we left the March 9th pre-NDA meeting with the FDA with a very, very clear direction that we were -- in the United States we're going to be regulated solely as a drug.

Larry Haimovitch: Great. Second question, on the CE mark discussion you just had, that timeline you gave seem from my memory to be pushed out a little bit from what I remember last, has that changed much over the last couple or three months or I just missed that discussion?

Eamonn P. Hobbs: Well, it did move out sometime in the last six months by a little bit in that the notified bodies we were working with felt that the device side of the equation in Europe was going to be more appropriately regulated as a Class 2(b), which is the most stringent level of Class 2 device regulatory pathways, which changed our status from being able to self-certify and approve our own device based on our own quality system, to having to have the dossier self-reviewed and approved by the notified bodies and competent [ph] authorities. So instead of being able to do things in parallel, we had to go to doing things in series where we have to get our quality system validated and certified, which actually is underway and then we have to, once we have that, then we have to file our complete dossier. So that did add a few months to the European approval timeline.

Larry Haimovitch: And then one last question and I'll jump back in queue, and that is, in doing some due diligence on liver cancer beads [ph], talking to one physician recently, Eamonn, and this would probably be more of a question for the doctors, actually, he said, you know, he'd thought PHP was a very interesting approach but he thought it was very time consuming, very cumbersome and will be for some hospitals and physicians maybe not as easy a procedure as you would like to see and therefore the adoption could be a little slower. Just wondering if any of the doctors who were in the trial might want to comment on that?

Dr. Eric Whitman: I think -- my turn to comment, guys.

Kris Kandarpa: Yes, it is, Eric.

Dr. Eric Whitman: There's no doubt it's more time consuming than some of the alternative procedures that had been used for liver cancer, like just putting a catheter into the hepatic artery and injecting chemotherapy or radioactive beads. On the other hand, I would challenge any of the doctors to show any evidence that any of those treatments are anywhere near as effective as PHP. And judging by the calls and emails that we get and Jon Zager was talking, Dr. Zager was talking about patients figure that out pretty quickly, and this is so, the magnitude and effectiveness is so impressive that I think those other procedures will be challenged to show that they're even close. And I think that this is something hospitals will have to do [unintelligible] or they will lose [ph] those other patients.

Larry Haimovitch: Got it. So the efficacy will trump any timing issues or any...

Dr. Eric Whitman: Yes, you know, yes, it's more, there's more logistical issues, it does take more time, but if you have patients do you really care.

Larry Haimovitch: No, of course not. What's the order of magnitude of time in your opinion versus these other therapies we were talking about?

Dr. Eric Whitman: I don't know RSA [ph], but I can tell you to put a catheter, for the image [ph] we all just put a catheter into a selected hepatic artery and inject chemotherapy or beads or any agent right into the liver. It's probably under an hour procedure and I'd be interested to hear what the other doctors feel. Our PHPs are typically somewhere between three and four hours and we could probably do two a day in the same room.

Larry Haimovitch: Mm-hmm. Okay. So there is a significant time change, but as you say efficacy's what matters.

Dr. Eric Whitman: Yes.

Larry Haimovitch: Great, thanks.

Eamonn P. Hobbs: Any other comments from the doctors?

Dr. Sanjiv Agarwala: No, I agree with that. I think, you know, it certainly does take coordination, it requires planning, and there's a learning curve, but it's very doable and Eric is right, if it's efficacious you do it, you know. I mean obviously this was about the same as other things we have and that will be a big issue but I certainly don't think it's an issue given the data and the fact that, you know, taking three or four hours for something like this, it's not that big an issue. You know, basically even for the other things that we've talked about, like RFA and beads, that takes planning too and even though the actual procedure might take less, when you add it all up together and the time it takes to get them there and do everything and it's not that much different, in my experience.

Larry Haimovitch: Yes. Great. Thank you very much.

Kris Kandarpa: I'd just like to add one comment as an international radiologist. Even those procedures, as Dr. Agarwala was alluding to, depending on how much, how many places you have to put the catheter they can take longer. And I can also tell you that the actual part of placing catheters is rather simple, as all the physicians on the panel will attest to. So the three hours we are referring to is skin to skin in the room and out of the room.

Dr. Sanjiv Agarwala: Correct.

Operator: Thank you. And our next question comes from the line of Rick Elkin [ph] with OPCO. Please go ahead.

Rick Elkin: Hi. Just had a question, the other treatment that received some notice at ASCO was the telamumab [ph] and I just wanted to get some sense from the doctors, how this would be used in metastatic melanoma and compared to chemosaturation with Melphalan? And also, would it make sense to use the telamumab in a chemosaturation regimen?

Dr. Sanjiv Agarwala: I can perhaps start taking this one. And basically ipilimumab [ph] is a very different type of therapy as I'm sure you know. It's an immune therapy and it is really in terms of the data presented at ASCO, these are patients who in terms of comparing ipilimumab immune therapy to a vaccine, so essentially was done even though there was a combination arm, it's been shown convincingly that the ipilimumab has an improved overall survival. So it's definitely a step in the right direction. I've done a lot of work with ipilimumab and continue to do so and I'm a believer in that drug, so I can be unbiased when I say that. But it's a really good first step but by means is it something that's going to be curative in the large percentage of patients. In fact, if you look at the response data, it's less than 10%. And certainly we haven't really teased out the different areas of response but all our experiences with that agent, liver metastasis don't respond very well. So, I consider the two treatments to be completely complementary to each other, and therefore, as you ask the question, the same question we're asking ourselves, indeed, this would be a terrific thing to combine. And you know if you can get some kind of a long term overall survival benefit with non-hepatic disease patients that have hepatic disease as well with ipilimumab and then fold [ph] in the PHP, a s we've talked before, about debulking [ph] the liver, I think they make excellent sequential approaches. I'm not sure you can do them concurrently, but definitely they will be approaches that could be done back to back.

Rick Elkin: Okay. And if I could just ask one other thing. On the primary liver cancer and colorectal cancer, would you expect them, were they metastasized to the liver, would you expect them to be affected the same way by chemosaturation with Melphalan or is that really just for melanomas that have metastasized to the liver?

Dr. Jonathan Zager: I think there's some good Phase 1 and 2 data as well as open hepatic profusion data that's out there that suggests that colorectal metastasis and other histologies will respond very well to high dose Melphalan regional profusions. I think that's well established, especially in the open hepatic profusion data. Melphalan as an alcolating [ph] agent in super high doses in a regional profusion should be able to have it, have noticeable effects on most if not all histologies.

Operator: Thank you. That is all the time we have today for questions. At this time I'd like to turn it back over to management for closing comments.

Eamonn P. Hobbs: Well, thank you, everyone, and I'd like to thank the panel for taking time out of their busy schedules to join us today. It was very enlightening and I'd like to thank everyone who joined the call for all your interest in Delcath. Have a great day.

Operator: Thank you. Ladies and gentlemen, if you'd like to listen to a replay of today's call, please dial 303-590-3030 or 1-800-406-7325, enter the pass code 4317816. Once again, those numbers are 303-590-3030 or 1-800-406-7325, enter the pass code 4317816. That concludes today's Delcath Systems Update Conference Call. Thank you for your participation. You may now disconnect.

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