### 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): August 3, 2010 (July 29, 2010)

### **DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-16133 (Commission File Number) 06-1245881 (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 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

#### Item 7.01. Regulation FD Disclosure.

On July 29, 2010, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss financial results for the second quarter and 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.

The following exhib	oit is filed herewith:
(d) Exhibits.	
Exhibit No. 99.1	Description Delcath Systems, Inc. Conference Call Transcript
	3

Item 9.01. Financial Statements and Exhibits.

### **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: August 3, 2010 By: /s/ Peter J. Graham

Name: Peter J. Graham

Title: Executive Vice President, General Counsel

# EXHIBIT INDEX

# Exhibit No. Description

99.1 Delcath Systems, Inc. Conference Call Transcript

# DELCATH SYSTEMS, INC., #4338101 DELCATH SYSTEMS, INC. - 2Q2010 FINANCIAL RESULTS CONFERENCE CALL

July 29, 2010, 4:30 PM ET Chairperson: Doug Sherk (Mgmt.)

Operator:

Ladies and gentlemen, thank you for standing by. Welcome to the Delcath Second Quarter 2010 Financial Results Conference Call. During today's presentation all parties will be in a listen-only mode. Following the presentation the conference will be open for questions. If you have a question, please press the star, followed by the one on your touch tone phone. If you would like to withdraw your question, please press the star, followed by the two. If you are using speaker equipment, please lift the handset before making a selection. This conference is being recorded today, Thursday, July 29th of 2010.

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

Doug Sherk:

Thank you, Operator and good afternoon, everyone. Thank you for joining us today for Delcath System's Second Quarter 2010 Financial Results Conference Call. 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 company's website for a limited time.

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 the company's 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, the company's ability to enter into agreements with foreign partners and the corresponding revenue associated with such foreign markets, actions by re gulatory authorities, changes in the healthcare environment, including reimbursement, and overall economic conditions and uncertainties regarding 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.

For today's call, we have encouraged investors to submit written questions through noon Eastern Time today. For those of you who did submit questions, we appreciate your participation. Management has attempted to answer many of your questions in their remarks; following those remarks the call will be opened up for the live question-and-answer session, and time permitting, we will also try to answer all the written questions not already addressed. We request that each participant during the live Q&A session limit themselves to two questions and then requeue to ask additional questions. We thank you in advance for your cooperation with this process. Given management's schedule, we have allotted 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; and Kris Kandarpa, our Chief Medical Officer. I'd like to start off by thanking those of you who submitted your questions for today's call. We look forward to answering as many of them as time allows today.

Since we last talked with you on June 15th, our team here at Delcath has continued to execute our strategy to complete the development and gain regulatory approval to market our Chemosaturation System for percutaneous hepatic perfusion (or PHP). In today's call, in addition to discussing our second quarter financials, we'd like to update you on the progress in regulatory affairs, clinical publication and recent additions to our medical advisory board and our Board of Directors. Since the presentation of the Phase 3 trial data at ASCO in early June, we have received consistent, positive feedback from clinicians about the data developed from the trial. The highly successful trial results showing the benefits of the Chemosaturation System for PHP for both those patients that had treatment from the start with the PHP system as well as those that crossed-over from best alternative care, were reviewed during a call we conducted on June 15th. Work continues on a submission of the trial's results to a top tier peer reviewed medical journal and we are hopeful that such a submission will be completed during the fourth quarter of this year. Assuming the submission is accepted, we are optimistic that publication of the trial's data would come in Q1 2011.

Our team also continues to prepare the remaining four modules of our FDA submission. The first module, which was the Phase 3 trial data [Correction – the first module contained non-trial data, the Phase 3 clinical trial data will be included in a future module], was submitted in late April. The remaining four modules are scheduled to be submitted on a rolling basis to the FDA and we expect that the process will be completed in the fourth quarter with October remaining as our target. If the FDA accepts the submission, we would anticipate approval to market the Chemosaturation System via PHP system in mid 2011.

For Europe, we are on track to complete our Class III medical device CE application, quality system and GMP audit and submit our technical file by the end of the year. As we prepare our FDA submission and CE Mark application, the various regulatory bodies will be conducting quality system and facility audits of our Queensbury facility as part of the review process. We expect to be fully prepared for the audit process, which will take place this summer and fall.

During our partnering initiatives for the Asian market, we continue to conduct negotiations with potential international partners, and as we noted back in June, the interest in our technology increased subsequent to the ASCO Phase 3 trial data presentation. We will announce any developments as they occur.

Many of you have asked us about the status of our Phase 2 trial at the NCI. The trial is still ongoing and our intent remains to close the study soon and submit for publication prior to the end of the year.

Recently we were able to attract five distinguished physicians to join our medical advisory board. Joining the Delcath MAB are: Dr. Yuman Fong of Memorial Sloan Kettering Cancer Center; Dr. Jeff Geshwin of Johns Hopkins University School of Medicine; Dr. John Kaufman of the Dotter Institute of the Oregon Health & Science Center; Dr. James Pingpank Jr. of the University of Pittsburgh Medical Center and Dr. Jonathan Zager of the Moffitt Cancer Center. One of the MAB's missions is to evaluate potential applications of our Chemosaturation System therapy in new cancer indications. With these additions, our MAB now consists of ten leading clinicians on the cutting-edge of oncology research and treatment. We look forward to their guidance and expertise as the company begins to transition from development stage to commercialization.

We also recently announced a transition on our Board of Directors. We are very pleased that Doug Watson, a former President and CEO of Novartis Corporation, the US subsidiary of Novartis AG, agreed to join our Board. Doug brings extensive experience in pharmaceuticals and the pharmaceutical industry. He currently serves as the Chairman of the Board of OraSure Technologies, as well as on the Board of BioMimetic Therapeutics, Dendreon Corporation, and Genta. We look forward to his contributions to Delcath.

Additionally, we'd like to thank Rich Taney for his service to the Board. Rich served as CEO of the company from December 2006 through July of last year, and while he's stepping down from the Board, we're delighted that he'll continue to serve as a consultant to senior management and the Board of Directors.

Now, I'd like to turn the call over to Dave McDonald, our CFO, who will review our financials. Dave?

Dave McDonald:

Thanks, Eamonn, and good afternoon, everyone.

As many of you know, we filed our 10-Q report for the second quarter results this afternoon, and I'm happy to report that our balance sheet remains very strong. The cash position as of June 30th was approximately \$27.2 million and we continue to have no debt. During the three months ending June, our cash burn, our monthly cash burn was approximately \$2 million per month.

Turning quickly to the income statement, we reported an operating loss for the three months of \$8.3 million. Now, it's important to note that approximately \$1.6 million of that was related to non-cash charges, basically, FAS 123 for stock compensation expense. Given we're adding a number of people and the stock price is rising, that non-cash charge was higher than what we were anticipating at the beginning of the year. As we continue to move the organization forward, research and development expenses increased about 109% to \$4.6 million, reflecting additional headcount as well as spending on our FDA submission. And included in the operating expenses was a one-time purchase of raw materials of approximately \$600,000. Again, it's important to note that as a development stage company, all of that gets expensed, it doesn't go on the balance sheet as inventory.

So with that brief update, I'd like to turn the call back to Eamonn.

Eamonn P. Hobbs:

Thanks, Dave. Before opening up the call to questions, I'd like to remind our audience that we will be presenting at the Wedbush Securities Life Sciences Best Ideas Management Access Conference in New York, New York on Tuesday, August 3rd at 3:00 pm Eastern Time. We are also presenting at the Canaccord Genuity Growth Conference on August 12th and we'll announce those details soon. Both events will be webcast.

Operator, we're now ready to take questions from our telephone audience.

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 your question, please press the star followed by the two. If you are using speaker equipment, please lift the handset before making your selection. One moment please.

And our first question comes from the line of Ken Cacciatore [ph] with Cowen & Company. Please go ahead.

Ken Cacciatore: Hey, guys. It's Ken.

Eamonn P. Hobbs: Hey, Ken. How are you?

Ken Cacciatore: Good, how are you doing?

Eamonn P. Hobbs: Good, thank you.

Ken Cacciatore:

So, thanks for the updates and also congratulations as you continue to bolster the clinical and scientific strength. I was wondering if you could [talk] about, as we're getting closer now to commercialization, maybe some of the steps you're taking could bolster the commercial infrastructure, and that's just one part of it. I know you touched upon the manufacturing, so maybe just a progress update on the commercialization strategy and what you're doing? And also, maybe if you could give us a little bit of sense as we get closer about, you know, pricing decisions? Maybe discuss with us a little bit of the homework you've been doing more recently? Thoughts about your pricing, maybe, like I said, work you've been doing in that regard, maybe initial conversations with payers to give us a better sense of what's happening there as well?

Eamonn P. Hobbs:

Sure. The programs we have going on right now in commercialization are pretty extensive. Our plans in the United States are to go direct, have a direct sales force that we will be starting to put together in the first half of 2011. We've already built up a sales and marketing organization from the top down. Agustin Gago is our Executive Vice President of Global Sales and Marketing and he is actively putting together his team. We have already built up a strong infrastructure of a marketing team, and we'll continue to expand that team as we grow closer to FDA and OUS regulatory approvals.

Our plan in Europe is to go through stocking distributors with a few countries where it makes sense going direct. So, Agustin and his team has been working on putting together the distribution network for stocking distributors in various European countries, and we feel very comfortable that those will all be on board prior to CE Mark approval, which we'd anticipate around mid 2011.

And Asia, of course, we're working on strategic partners who will also be our exclusive distributor and our intent is to have very close partnerships in the major markets there. We've already set up our first one in Taiwan and are very actively pursuing and negotiating deals in China, Korea and Japan.

So, the pricing, moving on to pricing, our anticipation is that our average selling price for modeling purposes for the Delcath System in the United States would be \$20,000, and that would include both the drug, Melphalan, and the drug delivery system, which is still regulated as a, under the drug approval and drug labeling. And, why we believe that's a good number to work with is we've looked at comparable treatments for liver cancer and feel that a list price of approximately \$100,000 for an orphan drug is a good rule of thumb for a treatment course, and factoring back into two and a half treatments per patient, we think that the \$20,000 average selling price is a very conservative estimate for modeling purposes.

OUS, it varies whether we're direct or through a distributor and varies by country, but the average selling price will -- and it may or may not include the drug. So, again, depending on the country. So, that one is a little more complex to model out. But we would expect that we would have still very attractive margins, even in gross margins, even in -- through a distributor network.

And last, with regards to payers, we continue to work on our plans for a reimbursement. We still get feedback from the clinical sites that there are existing codes, which they believe will provide adequate or at least adequate reimbursement to make the procedure attractive. And we are preparing to get, as a back-up plan, just in case that does not prove to be true, we are certainly prepared to get our own codes. But, at this stage, I think it looks pretty clear that existing codes will be what's used at least initially.

Operator: Thank you. Our next question comes from the line of Matt Dolan with Roth Capital Partners. Please go ahead.

Matt Dolan: Hi, guys. Good afternoon.

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

Matt Dolan: Good. Maybe first question on the spend in the quarter. You know, did that ramp as you ran [ph] or can you just talk about kind of

cash usage and expenses here as we go into the second half of the year into the commercial phase?

Dave McDonald:

Yes. Matt, it's Dave. Obviously, monthly it'll fluctuate depending upon what hits. If you looked at the first couple of months of the quarters, consistent with the 1.8 that we've been seeing for the last eight or nine months and then it was higher in that third month of the quarter largely because of that one-time spend on raw materials. So, that said, obviously we've got more people

ending the quarter. I think we ended the quarter at about 32, so. And I think sitting here today we're at 38 or 39. So, as we've said, we anticipate, as we get closer to commercialization, headcount will continue to go up and burn will move north.

Matt Dolan:

Okay, that helps. And then just thinking back to the data that came out at ASCO, can you maybe just, Eamonn, your anecdotal feedback from talking to physicians and that could be potential customers out there. You know, what's your perception of how the data was received, how they expect labeling might proceed with the FDA and has your confidence level increased, decreased or

remain the same out of seeing that full data set?

Eamonn P. Hobbs: I would definitely say our confidence level has increased. You know, with the amount of noise that was associated with the ASCO presentation, we certainly went -- we did a deep dive into our database and a deep dive into our future customer base to make sure

that all our channel checks were still showing the same. We came away from that really very, very comfortable. Even more comfortable that we had a very robust trial with excellent data and that our market assumptions were validated and we -- you know, being a marketing guy, the way to validate markets is to talk to the market and ask them what they're going to buy and what -- and how much they're going to buy of it and will they associate a value commensurate with the price. So, you know, we're constantly doing that and -- because it is a moving target in any market, but we've been very pleased with the validations th at we

continue to receive. On a scientific level, Kris is here. Maybe he could comment on that.

Kris Kandarpa: Sure. Yes. As far as our clinical friends are concerned, they're very excited about the results be they medical oncologists or surgical oncologists. I just got back from the European Congress of International Oncology and we had a workshop there that was

very well received and a lot of interest in our booth at the show.

Matt Dolan: Okay, great. So just kind of a follow-up on that then, your perception now relative to ocular and cutaneous patients, is that, you

know, surgeons or physicians will adopt for those applications kind of regardless of labeling with FDA.

Kris Kandarpa: Correct.

Matt Dolan: Okay. And then finally, Eamonn, you mentioned an increased level of international partnership interest out of ASCO, does that --

maybe you can just help us bracket the timeline of an agreement? Have you progressed in those discussions or what type of

milestones should we look for that might hint that one of those agreement's coming?

Eamonn P. Hobbs: Well, these agreements, you know, is, as recent history has shown, very, very difficult to time. We believe we're making very, very

solid progress on multiple fronts and we're extremely optimistic. But they're not finished 'til they're finished, and we're -- and no one will be more pleased to announce the deal than I will be. But we'll -- I couldn't -- I wish I could venture a realistic estimate as to when we'll have one of these closed. But it is very steady progress on multiple fronts. Very, very serious interest and some very

consistent interest. So, you know, we're -- you never want to count your chickens before they hatch, but we're optimistic.

Matt Dolan: Great. Thanks for the time, guys.

Dave McDonald: Thanks, Matt.

Operator: Thank you. Our next question comes from the line of Brooks West with Craig-Hallum Capital. Please go ahead.

Brooks West: Hi, can you hear me?

Eamonn P. Hobbs: Hey, Brooks. How are you?

Brooks West: I'm doing well, thanks. I wanted to push just a little bit more on reimbursement. You know, you're talking about adequate existing

codes, are those the IHP surgical codes that you're referring to? And then I'm wondering as you, you know, obviously it's early days in the process, but as you look out to commercialization, anything else you can talk about in terms of, you know, the environment? I'm thinking about even, you know, what's happened at Dendreon [ph] with national coverage analysis out of CMS,

just any other detail there would be great.

Eamonn P. Hobbs: Sure. The codes that exist that can cover our procedure are numerous. The -- including the surgical IHP. But it's much broader

than that and, you know, depending on facts and circumstances, different codes can be used. We're putting together that menu of codes that we're getting through surveying hospital customers to nail it down, but it isn't as simple as there's just one code. It's a whole list of codes that can be applied in varying orders to be the most appropriate for the facts and circumstances of each individual patient. These will be, at least at the beginning, inpatient procedures, so there's DRGs, and, you know, which are pretty

global in their scope and they're very high reimbursing.

Brooks West: Okay. Let me switch to -- Kris, any update on the filter program and we were talking around, you know, ASCO, you know, maybe

a next generation filter might be able to completely remove Melphalan prior to depositing the blood back in the body. Any update

there?

Kris Kandarpa: Yes. Brooks, so we do have our R&D facility up in Queensbury and we started working on, you know, different media coatings

[ph] and filter housings, and we're I think on track to having a preclinical filter by the end of the year.

Brooks West: And is that still the thought that you should be able to improve on the removal of the drug?

Kris Kandarpa: Yes, what I think it does, if you do that it allows the physician -- gives the physicians a lot more options to go after other lesions

elsewhere in the body with far fewer [ph] systemic toxicities.

Brooks West: Okay. And then --

Eamonn P. Hobbs: One thing to add to that, Brooks.

Brooks West: Yes.

Eamonn P. Hobbs: Because I can imagine that it might come up, and that is, from a regulatory perspective, we're going to seek approval for what was

used in the clinical trial, and then seek approval post-FDA approval of the system that was used in the trial, which generated all this great data. We're going to definitely be pursuing approvals of supplement -- or of improvements on the system. In a normal or customary supplement fashion with NDA supplement, so. We're not mixing apples and oranges in our initial submission, so --

which is the right way to do it.

Brooks West: Sure. Good. Thanks. And I guess just last question. You know, Dave or Eamonn, you know, I'm frequently hearing from people,

you know, since the breakdown [ph] of the stock since ASCO, you know, we haven't seen any insider transactions. Has the

window just been closed for you guys? Any detail there would be great. Thanks.

Eamonn P. Hobbs: This is Eamonn. I'll let Dave speak because he has more control of the window than I do. Yes, because I'd like to see the window

open all the time, but clearly you've hit the nail on the head. Speaking as one insider, I've been very frustrated in not being able to buy because the window's been closed and the decision on whether the window is open or closed, is impacted by timing issues as well as a committee of our CFO, Dave, who'll get to speak ahead [ph] of our audit committee and Peter Graham, our internal counsel and outside counsel, as he sees fit to bring in. So, yes, there's a lot of interest but we have not had a window since

ASCO. And, over to you, Dave.

Dave McDonald: Well, thank you very much. Yes, I will confirm there's been no window since ASCO. And as you know, Brooks, I mean, you get

your normal quarterly periods around the results where they're closed and we take a fairly conservative view on that for development stage companies as well as in, you know, if there are any pending things that could be material, so. And we've been

in a closed window given the Q2 results, you know, since just after ASCO.

Brooks West: So I guess just the follow-up there is, when might we see that window open up?

Dave McDonald: Yes. Can't comment on that, but good try.

Eamonn P. Hobbs: Yes, obviously if there's any material non-public information going on, then we can't open the window. So in the -- I think I might

be frustrated for some time to come.

Dave McDonald: I guess you can imagine, given the stage [ph], right, there are a lot of things going on as we continue to have discussions and other

developments, it's just -- and, you know, they're all good things but it is what it is and therefore it's sometimes a little frustrating

from our standpoint that we can't take advantage of what's going on. But there you have it.

Brooks West: Okay. Thanks, guys.

Dave McDonald: Yes.

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

Jim Morris: Hi, this is Jim Morris. I'm calling in for Jason.

Speaker: [unintelligible].

Jim Morris: I just want to follow-up on the feedback that you've been getting from physicians. You said a little bit in the beginning about how

it's been positive, but, you know, you can't be positive for all of them. Some of the guys that are pushing back, what has been their

concerns and how are you addressing those?

Eamonn P. Hobbs:

Well, you know, frankly, we have not gotten a lot of pushback. We've been going through our channel checks vigorously and the issue that was presented by the discussion at ASCO about overall survival, you know, the channel checks, we keep getting very consistent feedback on was that -- well, the trial was never designed to provide robust overall survival data because of the cross-over provision. So, actually, there's just no negatives in that trial associated with overall survival and it's not fair at all to say, well the trial is flawed in some way because it didn't provide overall survival data because it was never intended to, so. And then, coupling with that, the context of an FDA approval, the trial's being conducted under a special protocol assessment, that clearly specified, called straight out that the overall survival data would be confounded by the cross-over provision. 60; So, you know, we -- speaking for me, I haven't gotten any negative feedback. Over to you, Kris.

Kris Kandarpa:

Yes. You know, the physicians understand the study design and they also understand the details of the criticism that discounted it entirely because it was not at all relevant to the present discussion of our study. And so, to echo Eamonn, I've not gotten any pushback per se, you know, from physicians to defend anything.

Eamonn P. Hobbs:

The only -- I'm just searching my memory bank -- the only negative feedback that I can remember over the last six months, before ASCO and after ASCO, was associated with an incomplete understanding or a complete misunderstanding of what we were trying to do. And maybe that's worth discussing in, a little bit, in that, some medical oncologists and other specialties as well, didn't quite understand that we were -- what we were trying to do, in that, we were trying to complement systemic therapy for metastatic disease by treating the liver where systemic therapies really don't have much of an effect, if any. And, there was some misunderstanding that we were trying to replace systemic therapies with regional [ph] therapy, which has never been our intention. And, once that was cleared up, that, of course, cancer is -- metastatic cancer is a systemic disease and of course you need to trea t it systemically, but the problem is when the disease gets into the liver, the patient typically dies of liver failure and systemic therapies aren't very effective. So once we got the idea across that this is a new tool to complement systemic therapies; not replace them in any way, then they got it right away. So that's really the only negative feedback I've heard over the, over my tenure. And, of course, as the ASCO data is disseminating, we're much more free and open to discuss and educate, so, you know, hopefully we can clear up any misconceptions and clarify things.

Jim Morris:

Okay. I think --

Dave McDonald:

Jim, the only -- this is Dave. The only other thing I would add to that is, I certainly haven't gotten anything from a medical standpoint. I think, you know, some physicians have said, just asked the reimbursement questions, you know, making sure they get paid and utilization's just more of a marketing pushback not a clinical pushback.

Jim Morris:

Okay.

Operator:

Thank you. Ladies and gentlemen, as a reminder, if you have a question, please press star, one on your touch tone telephone. If you would like to withdraw your question, please press the star, two.

And our next question comes from the line of Curtis Hogue with Discovery Capital. Please go ahead.

Curtis Hogue:

Hey. Thanks for taking my question. First, would you be so kind to discuss the independent core lab results for the overall response rate as well as the overall progression free survival in the other secondary endpoint in the clinical trial?

Kris Kandarpa:

Sure. The core lab data was what was released in April, and that is data that's based on imaging studies that were vetted independently by a core lab, as opposed to the investigators' team, investigators' radiologist interpretation, if you will. If you remember the PHP hepatic progression free survival was 214 days versus 70 days for the BAC [ph], which was again with a p-value of 0.001 and a hazard ratio 0.46, which is extremely good. Now that is what the FDA cares for and that's what we're going to present them, obviously, along with the investigator data that we released at ASCO. And, that had to be done that way because the ASCO abstract went in a lot sooner and it's not unusual, it's not an unusual practice as a matter of fact. Having said that, when you talk about the secondary endpoints and overall progression free survival and so forth, the conclus ions you draw are not at all changed by this one core lab analysis. Does that answer your question or?

Curtis Hogue:

So the -- just so I understand this -- the secondary endpoints, the overall response rate, the overall progression free survival and the other secondary endpoint are all the same, as assessed by the independent core lab as they were by the investigator's?

Kris Kandarpa:

Pretty much, yes.

Eamonn P. Hobbs:

Yes, the numbers change slightly but not materially.

Kris Kandarpa:

And the statistical validity does not change at all, actually.

Curtis Hogue:

Okay. Thanks. And then, just a follow-up. In Dr. Pingpank's presentation, he disclosed the toxicities from 40 of the patients in the PHP arm but didn't disclose the toxicities in the patients who crossed-over from the BAC arm. Were those -- were the toxicities similar to the patients in the PHP arm, including the number of deaths [ph] and the grade 3, 4 and 5 toxicities? Or can you talk quantitatively or qualitatively about those?

Kris Kandarpa:

Yes. So, you know, if you look at patients who are exposed to Melphalan, but also include patients who crossed-over, the results are not any different at all.

Eamonn P. Hobbs:

And the reason Dr. Pingpank presented the way he did was intent to treat.

Kris Kandarpa:

Exactly. Yes, he used -- just like he presented the overall survival, it was all an intent to treat analysis; which means you attribute whatever results you're reporting to where the patient -- to the group that the patient began in.

Curtis Hogue:

Okay. And so there were how many total deaths in the study attributed to the study drug?

Kris Kandarpa:

There were a total of five. And, you know, the -- but three of them were attributed to the drug. So the -- and there were a total number of 67 patients who were exposed to PHP.

Curtis Hogue:

Okay. Great. Thank you very much.

Kris Kandarpa:

Sure.

Operator:

Thank you. And at this time I'm not showing any further questions. Management, please continue.

Eamonn P. Hobbs:

All right. Well before concluding today's call, we'd like to respond to shareholder questions submitted in advance that have not already been addressed. And thank you, by the way, for all your questions and we're looking forward to answering those.

The first question that we're going to answer is, what is the status of the expanded access program? And is this program now accepting patients?

And as background, we received FDA approval to open an expanded access protocol before we concluded the Phase 3 protocol, which would have allowed more [ph] patients to be treated prior to -- continuing to be treated prior to FDA approval. The status of the trial is that we have decided not to open that trial. And this was a very difficult decision for us to make, in that, we certainly wanted to provide patients access to the PHP system prior to FDA approval, but the Phase 3 results were so good and our likelihood of -- our belief and likelihood of getting FDA approval is so high that we felt that the best way to provide access to the most number of patients would be to get FDA approval in the most expeditious way. And we wanted to focus all of our resources on getting FDA approval instead of dividing them between getting FDA approval and conducting the access trial in parallel with that. So, you know, it's one of those things where we would have liked to have done it but it really would not have added any incr - we didn't feel have increased our likelihood of getting FDA approval because we already had more than enough in our -- from this Phase 3 trial data since the data was so robust.

Next question is, what is the outlook on financing and partnerships? And, I'll hand that over to Dave.

Dave McDonald:

All right. I'll take the financing question first. As many of you know, listening to us since last fall since we did the raise then, we've said we'll require additional capital prior to becoming cash flow positive. With that said, though, we don't comment on timing and where it might come from. You know, clearly, we have many options with respect to the capital markets, we continue to talk with potential strategic partners. As Eamonn mentioned earlier, the timing on that is uncertain, and so, all I can tell you is, yes, we will require additional capital before becoming cash flow positive, but I don't know when or from what source it comes from.

Eamonn P. Hobbs:

Next question is, is the company still reluctant to self-promote success stories, such as Linda Campbell's [ph], because the company is still in the pre-approval stage?

And the answer to that is, patient testimonials are readily available to us, in that, there are many patients who have benefited from the PHP system and are doing very, very well. The -- but during the approval phase, it is very, very unseemly for a company to utilize those stories to bolster itself. So, we'll have to leave that to patient advocacy groups and the patients themselves to put the word out, which they do. And certainly we're all encouraged by those stories, but we need to be very quiet as a company with regards to the benefits of the system outside of educational activities associated with trial data and the like. So, we can't promote but we can educate during the quiet period, and we need to stick to our guns there.

Next question, what is the status of our ongoing relationship with Chi-Fu [ph] Trading Company Ltd., specifically are there any trials being developed? And if there are, what are the timetables for the start of these trials? And what would the trial protocol look like?

The status of our relationship with Chi-Fu is very strong. We are moving along with them. Part of our relationship with them is to partner with them to conduct a clinical trial in Taiwan on primary liver cancer, hepatic cellular carcinoma, and we would expect that that trial would be initiated sometime in 2011. We are working on trial protocols now. And, Kris, maybe you could share something on that?

Kris Kandarpa:

Sure. We've decided that we want to do a Phase 1 and a Phase 2 trial there as well because the population is different from the Western population in terms of size and so forth, tolerability of the drug, perhaps. So we are preparing those protocols at this moment.

Eamonn P. Hobbs:

Great. Next question is probably best answered by Kris. After approval for metastatic melanoma in the liver, what will be your top priority for fighting other cancers?

Kris Kandarpa:

Sure. To follow through, so when we get the melanoma approval or not waiting that long actually, we're going to pursue as closely after with the HCC [ph] trials, as we'd said, in Asia, but we will also be doing neuroendocrine tumors and establishing some utility there. And eventually we would like to, perhaps in the middle of next year or so, look at the colorectal mets [ph] to the liver.

Eamonn P. Hobbs:

Next question, what type of information was held back at ASCO in anticipation of possible journal publication? Should we expect to see updated [ph] results or a new analysis and different cohorts? Kris, do you want to--

Kris Kandarpa:

Yes. The kinds of results that were really not held back but rather we reserve for our publication, the secondary endpoint, the full, as a full set of five secondary endpoint, and some subgroup analyses that are allowed with the statistical analysis plan of the study.

Eamonn P. Hobbs: And next question, are there any efficacy analysis that were pre-specified in the statistical analysis plan that were not presented by

Dr. Pingpank at ASCO?

Kris Kandarpa: I guess the answer is yes, and we will be including it in the publications we see coming forward [ph].

Eamonn P. Hobbs: And what would they be?

Kris Kandarpa: The subgroup analyses would look at PHP versus BAC [ph] in terms of progression free survival, obviously, duration of response,

chemo [ph] and their toxicities and so on.

Eamonn P. Hobbs: Great. Well, we'd like to thank you all and participants for their feedback. Thank you all for joining us today and your interest in

Delcath. We look forward to keeping you abreast of our developments as they occur. Have a great day.

Operator: Thank you. Ladies and gentlemen, that does conclude our conference call for today. If you'd like to listen to a replay of today's

conference, please dial 303-590-3030 or 1-800-406-7325, using the access code 4338101. Thank you for your participation. You

may now disconnect.

**END** 

Delcath Systems, Inc. Page 07/29/2010