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): **May 13, 2013 (May 08, 2013)**

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)

566 Queensbury Avenue, Queensbury, New York, 12804
(Address of principal executive offices, including zip code)

(518) 743-8892
(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 May 8, 2013, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss the Company's financial results for the 2013 fiscal first quarter ended March 31, 2013 and recent operational highlights. 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: May 13, 2013

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

MAY 08, 2013 / 08:30PM GMT, DCTH - Q1 2013 Delcath Systems, Inc. Earnings Conference Call

CORPORATE PARTICIPANTS

Doug Sherk *Delcath Systems Inc. - IR Contact, EVC Group*
Eamonn Hobbs *Delcath Systems Inc. - President & CEO*
Graham Miao *Delcath Systems Inc. - EVP & CFO*

CONFERENCE CALL PARTICIPANTS

David Nierengarten *Wedbush - Analyst*
Mary Ellen Kay *Aegis Capital Corp. - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the First Quarter 2013 Delcath Systems Earnings Conference Call. My name is Derek, and I'll be your operator for today. At this time, all participants are in a listen-only mode. We shall facilitate a question-and-answer session at the end of the conference. (Operator Instructions)

As a reminder, this conference is being recorded for replay purposes.

I would now like to turn the conference over to Mr. Doug Sherk. Please proceed.

Doug Sherk - ***Delcath Systems Inc.*** - ***IR Contact, EVC Group***

Thank you, Derek, and good afternoon, everyone. Thank you for joining us today for this conference call and webcast to provide an update on Delcath's First Quarter 2013 results and recent developments.

A replay of the conference call will be available approximately two hours after the conclusion of today's call, and it will be available for seven days. The Operator will provide replay details at the conclusion of today's call. A live webcast of this call is also available at www.Delcath.com, and the call will also be archived on the website.

Before we begin, I'd like to remind you that some of the statements made during this conference call will contain forward-looking statements within the meaning of the safe harbor provision of the US Private Securities Litigation Reform Act of 1995. These statements are subject to certain risk and uncertainties, and actual results could differ materially than those projected in any forward-looking statement.

Factors that could cause actual results to differ are discussed from time to time in the Company's filings with the SEC, including our annual report on Form 10-K and our reports on Form 10-Q and 8-K. These documents are available on the Investor Relations section of our website, and we encourage you to review the material. The Company has no obligation to publicly update or revise these forward-looking statements to reflect the events or circumstances after the date they are made.

Participating on today's call are Eamonn Hobbs, President and Chief Executive Officer, and Graham Miao, Executive Vice President and Chief Financial Officer.

Following their opening remarks, we will open the call to questions from analysts and institutional investors. To maximize the time allowed for Q&A, please ask two questions, and if you have additional questions, please re-queue to ask those additional questions.

For webcast participants, questions can be submitted electronically via the webcast interface, and questions will be summarized and addressed. Feel free to send us your questions during the course of this call, and we'll summarize and address them during the Q&A session.

And with that, I'd like to turn the call over to Mr. Hobbs.

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***
Thanks, Doug. Good afternoon, everyone, and thanks for joining us today.

Of course, the most significant development at our company since we talked with you in early March was last Thursday's highly disappointing and surprising vote by the FDA's Oncologic Drugs Advisory Committee, or ODAC.

This afternoon, we'll provide an update on the ODAC panel outcome, an overview of our strategy going forward, including our clinical development program for other indications, and we'll provide a brief update on our EU commercialization. Graham will then review our first quarter financial results and provide an update on the availability and use of resources now and in the coming months.

Let's start with the ODAC panel outcome.

On May 2, 2013, the Oncologic Drugs Advisory Committee, ODAC, to the US Food & Drug Administration voted that the benefits of treatment with Melblez Kit do not outweigh the risks.

It's important to note that the ODAC Committee met solely to review certain aspects of the Melblez Kit NDA with the Generation 1 filter.

Equally important is to recall the Delcath NDA contained our Generation 2 filter included as a technical change in the chemistry, manufacturing, and control module of the NDA as a means to bring the enhanced safety of the Gen 2 filter to U.S. patients sooner. As a reminder, our European product is being commercialized with the Gen 2 filter.

The FDA briefing documents released before the meeting stated that the clinical trial data would be necessary to consider the Generation 2 filter for approval, indicating that FDA found our pre-clinical bridging studies were insufficient alone to approve the marketing of a device containing a new filter.

In addition to collecting clinical safety data, the FDA stated in a briefing document that the impact of a filter change on the efficacy of this drug device combination product is unknown and its efficacy must be established in a randomized clinical trial.

Upon learning of the FDA's position regarding the Gen 2 filter in the briefing document, we asked the agency for an urgent meeting prior to the ODAC, which was granted. During this meeting, we discussed our belief that since the filters are downstream of the melphalan delivery to the liver, they do not impact efficacy. We are awaiting the FDA's decision on what additional clinical data will be required to approve Gen 2.

Last Thursday, the ODAC panel was presented with the following preamble and associated question -- "Given the 5.4-month improvement in median hepatic progression-free survival, the three-month improvement in median overall progression-free survival, and a trend suggesting a detrimental effect on overall survival, along with the 7% incidence of toxic death and the observed risks of serious cardiovascular hepatic gastrointestinal and bone marrow toxicities for patients with hepatic-dominant metastic ocular melanoma, do the benefits of treatment with the Melblez kit, clinical trial version, outweigh the risks?"

We learned of the FDA's preamble to the final version of the question to the ODAC less than 30 minutes before the ODAC was convened. Despite the preamble, we firmly believe we showed that in a study whose protocol was approved by the FDA, the Melblez Kit has demonstrated a clinically meaningful benefit in both hepatic progression-free survival and progression-free survival.

To be specific, the Company respectfully disagrees that the, quote, negative trend, unquote, associated with the overall survival is a clinically relevant analysis since the overall survival data was confounded by the fact that the majority of the control arm crossed over to receive and benefit from the treatment.

We also disagreed with the FDA characterization of the safety data during the conduct of the clinical trials on several important points, and we have communicated these points to the agency.

For example, FDA's views related to patients' deaths due to treatment, effectiveness of the serious adverse event mitigation measures that were instituted in the protocol, and FDA's attribution of patient-related deaths due to the filter used were points that we felt were mischaracterized by the agency in their briefing materials released on Tuesday, April 30th.

We believe the exploratory, one-dimensional perspective associated with the FDA's presentation of these issues didn't provide a comprehensive perspective to the ODAC panel members, as well as the public.

Let me elaborate on our perspective. The FDA briefing document presented to the ODAC panelists noted that in the pooled safety database, which included both the Phase 2 and Phase 3 studies, 7%, or eight patients, of the 122 patients in whom the Melblez kit treatment was utilized, died as a result of treatment-related adverse reactions.

As we presented at ODAC, we did not agree that three of the eight patients were due to complications associated with the procedure as the treating physicians continue to be convinced that these patients died of disease progression.

We also did not agree with how the FDA further characterized the toxicity profile of the Generation 1 system as unprecedented. In fact, it should be noted that the 7% treatment-related deaths during the clinical trial using the Gen 1 filter is comparable to the currently FDA-approved labeling for the use in patients of intravenous melphalan. This labeling has been in place for more than 20 years. The adverse event-related deaths for IV administration of melphalan were 10% prior to the institution of GlaxoSmithKline's clinical trial protocol amendments, which lowered this rate to 3%, following the institution of the amendment.

This is not unlike the circumstances in our clinical trial. During the course of the clinical trial, we instituted numerous protocol amendments after a patient death, and after implementing these protocol amendments, there were no more deaths associated with the issues addressed by the amendments, indicating that the protocol amendments were effective in increasing the safety of the procedure.

However, despite the Company providing this important data to FDA and ODAC repeatedly, the FDA and ODAC panel did not acknowledge the improvement in safety profile after the Delcath protocol amendments were instituted.

A second point for your reference is that FDA has stated that the post-market safety profile of the Melblez kit treatment might equal the safety profile observed in clinical testing and that specified training cannot be expected to improve the risk/benefit profile beyond that observed in the clinical trials.

On this point, we strongly disagree with FDA. In reality, since the institution of protocol amendments in our trials and incorporation of these learnings into our global training program, which include 72 patients treated in our trials, as well as a total of 47 commercial patients in Europe and EAP compassionate use in the U.S., there have been no further deaths due to hepatic or gastrointestinal toxicities.

Regarding FDA's concern with patient deaths due to hematological toxicities, it should be noted that prophylactic use of bone marrow growth factor stimulants was rarely used during the conduct of the Phase 2 and Phase 3 clinical trial. However, in practice today, these are required.

Again, FDA and ODAC panel did not consider the improvement in the safety profile after these measures were instituted, which was surprising and disappointing.

In addition to the learnings resulting in protocol amendments and the proposed Risk Evaluation and Mitigation Strategies, or REMS, program, we are further addressing the safety issues related to platelet reduction and bone marrow suppression that we saw in our earlier clinical studies through the development of the Gen 2 filter and our subsequent inclusion of it in the NDA.

The combination of protocol amendments, proposed REMS, and Gen 2 filter, we believe, significantly reduces the side effect profile and have had a big impact on reducing the death rate, as is being demonstrated by our European experience.

We strongly disagree that the negative trend in overall survival presented by the FDA is clinically relevant. We believe that the reason the control arm of the study did very well is because of the majority of patients in it were provided the Melblez treatment.

It must be emphasized that because of the crossover provision of the trial design approved by the FDA, there is no statistically conclusive evidence that can be determined from the overall survival data one way or the other.

In summary, we are certainly committed to continuing our interaction with the FDA and doing everything possible to communicate and clarify our strong efficacy data set, the positive impact of our REMS program, and the specific patient need for Melblez.

While we work with the FDA on review of our application, we continue to move forward with our US Expanded Access Program, or EAP. Its focus is to provide eligible patients with access on a compassionate use basis, while our NDA is under review by the FDA. As a reminder, our EAP program includes the updated protocol, REMS program, and use of the Gen 2 filter.

Under the EAP, physicians at select U.S. cancer centers that participated in our clinical trials can use the Melblez kit and Expanded Access and Compassionate Use cases after they obtain institutional review board, or IRB, approval. These hospitals will provide a base of experienced procedure teams trained in the use of the Melblez kit.

Since initiating the EAP in January of this year, two patients have been treated with the Melblez in the U.S. under Expanded Access, with one of those patients receiving a second treatment, and five more patients are scheduled to begin treatment.

Before we continue with our corporate update, I'd like to thank the patients, their families, and the investigators for their participation in our clinical trials to date. We appreciate your ongoing support, which is critical to our goal of developing Melblez as a new therapeutic option.

In addition, I'd like to thank the physician experts who spoke at last week's ODAC to underscore the unmet need in treating patients with unresectable metastatic ocular melanoma in the liver and their passionate belief in the benefits to patients from the Melblez therapy. We appreciate their perspectives and commitment to evaluating new treatment options for this very rare and rapidly fatal disease that remains an essentially untreatable condition with no available standard of care.

And, importantly, I'd like to acknowledge the hard work of our clinical and regulatory teams in preparing for this ODAC meeting.

So now let me update you on recent progress on other fronts.

In April, we announced expanded efforts to increase our efficiencies and reduce our operating cash use this year. Under the program, workforce restructuring actions were expanded, which when combined with earlier workforce reductions, have reduced the Company's workforce by about 21% this year. Included in the most recent restructuring was the elimination of two senior-level positions in global sales and business development.

As part of the expanded efficiency program, Jennifer Simpson, PhD, MSN, CRNP, was promoted to the position of Global Head of Business Operations and now heads Global Sales, Marketing, Regulatory, Quality, Clinical Development, and Medical Affairs activities. Dr. Simpson joined Delcath in March 2012 as Executive Vice President-Global Marketing and has an extensive background in pharmaceutical development and oncology marketing, including responsibility for global product development in the oncology sector.

Meanwhile, business development efforts are now being led by myself and Graham Miao.

To further increase efficiency, we have changed the address of our headquarters to our upstate Queensbury, New York facilities and are planning to move our New York City operations to a more cost-effective satellite office in New Jersey as soon as we can sublet the New York City facilities.

In addition, as a result of last Thursday's ODAC development, we will be able to further reduce our cash utilization through reduced or eliminated consultant use, as well as other actions which are under active consideration.

Combined, the recent actions will significantly increase our organizational efficiencies, reduce expected cash burn in 2013, and Graham will provide the details in a few minutes on our financial expectations for the combined effects of these streamlining actions.

Also during the first quarter, we continued to make slow progress on implementing our commercial plan in Europe. To date, nine of 16 leading European cancer centers in our Training and Launch program have been trained and activated to provide Chemosat treatments, with the most recent addition being the NKI, or National Cancer Center, in the Netherlands.

These activated centers have treated 35 patients with a variety of cancers in the liver, a majority of which have been ocular and cutaneous melanoma liver metastases but have also included hepatocellular carcinoma, or HCC, Cholangiocarcinoma and liver metastases from breast cancer, gastric cancer, colorectal cancer, neuroendocrine tumors, and mucosal melanoma.

A critical driver of utilization growth for Chemosat in Europe and ultimately revenue will be the expansion of compelling reimbursement mechanisms for the procedure in each of the seven markets we are targeting.

Permanent compelling reimbursement in EU will take some time to secure, and in the interim period, we are seeking payment through various avenues, including new technology programs. For most countries, we will need the published Phase 3 trial manuscript reported by investigator-initiated trial data before submitting our applications. In the interim, we are working closely with experts at our partner hospitals on various interim mechanisms.

Now, I'd like to review our clinical development program and strategy going forward.

During the quarter, the Company held productive discussions with the FDA on designs for future clinical trials and new indications. As a result of these discussions and subject to agreement with the FDA, Delcath intends to initiate a pivotal trial in patients with hepatocellular carcinoma, which is known as HCC, or primary liver cancer, and expects to enroll patients in this trial by the end of 2013.

The primary endpoint for this open-label study would be overall survival with no crossover allowed, and this study will use the Gen 2 filter. We expect this study to enroll approximately 120 patients and anticipate this study would be about two-and-a-half to three years in length and cost roughly $14 million to $18 million.

Costs for this study would be spread over the duration of the study, with only about $2 million of the total cost being spent during the first year of the trial. More than 50% of the trial costs would be incurred during the last 12 months or so of the trial.

Assuming we get the go-ahead to move forward with this study, the cost impact would be relatively light in 2013.

The HCC opportunity clearly provides Delcath and our shareholders with an opportunity for a substantial return if we are successful with the trial versus the cost. HCC is the most common primary cancer of the liver, with approximately 750,000 new cases diagnosed worldwide annually. Furthermore, we believe there are well over 100,000 global new cases annually that have an unmet need that would be suitable for Chemosat treatment.

Based on this opportunity and unmet medical need, we are making HCC our top clinical development priority because we believe it offers the best value creation pathway for the Company.

We are also seeking to build clinical experience by sponsoring investigator-initiated trials, or IITs, with leading EU opinion leaders that have approached us to support new clinical research. We believe these IITS will help grow clinical experience with Chemosat at key centers and will support our effort to obtain compelling reimbursement for Chemosat.

With that, I'd like to turn the call over to Graham Miao for a review of our financial results, and then we'll take questions. Graham?

Graham Miao - ***Delcath Systems Inc.*** - ***EVP & CFO***

Thank you, Eamonn. Good afternoon, everybody.

Let me start by discussing the Company's financial condition. Thanks to the funding instruments we put in place, during the first quarter of 2013, we raised approximately $30 million through a combination of at-the-market, or ATM, equity offering, which raised the $20.9 million and through committed equity financing facility, or CEFF, which raised about $9 million.

We believe these funding vehicles offered the most efficient and less dilutive ways of capital raise compared to other alternatives. As a result, our cash position as of March 31, 2013 was strong at $42.8 million compared to $23.7 million at December 31, 2012.

Furthermore, as part of our continued efforts of effective cost management, our cash utilization in the first quarter of this year was $11.3 million, a 23% reduction compared to the $14.7 million used in the first quarter of 2012. The decrease in cash utilization during the first quarter was, in part, due to a reduction in NDA submission costs, as well as the elimination of EU commercialization start-up costs.

As a reminder, in early April this year, we implemented a plan to decrease our expected 2013 quarterly operating cash use to between $9 million and $10 million from the previously communicated range of $9 million to $12 million beginning in the second half of the year.

Post-ODAC, we are actively examining additional cost reduction strategies to reduce cash utilization even further.

Turning to the income statement, for the first quarter of 2013, we recorded revenue of $0.4 million, of which $0.3 million was related to the recognition of previously deferred revenue as a result of satisfying certain requirements of the Company's Research and Distribution agreement with Chi-Fu Trading Company in Taiwan. The remainder of the revenue was related to product sales.

Operating loss was $10.2 million, which included approximately $0.7 million in non-cash stock-based compensation expense, as compared with an operating loss of $14.6 million, including $0.9 million in non-cash stock-based compensation expense in the first quarter of 2012.

Selling, general, and administrative, SG&A, expenses were $6.1 million, a decrease from $7.4 million for the same period in 2012. The lower SG&A expense was primarily due to the elimination of EU commercialization start-up costs.

Research and development expenses were $4.5 million, a decrease from $7.1 million for the same period in the prior year. The lower R&D expenses reflect a significant reduction of NDA-related expenses.

As Eamonn mentioned, we expect the product revenue ramp to be slow until further progress is made on securing compelling reimbursement in Europe. We are continuing to work hard at establishing reimbursement mechanisms for the chemosat procedure in our target countries, which we believe in combination with increased clinical experience in Europe will help support future revenue growth.

With that, let me turn the call to the operator. We would like to open the call for questions.

QUESTION AND ANSWER

Operator

(Operator Instructions)

David Nierengarten, Wedbush.

David Nierengarten - ***Wedbush*** - ***Analyst***

Thanks for taking the question. The one question that we have is looking at your timeline to commercialization, you mentioned that you would look to a publication to support compelling reimbursement for Chemosat in Europe. Is there any timing on when that publication might happen? Thanks.

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

Thanks, David. The publication manuscript is with the authors, and it has been circulated amongst the authors and is in the final stages. So we are hopeful that it will actually be submitted for publication in the near future. We spoke with the lead author earlier today, and that's the latest information we have.

David Nierengarten - ***Wedbush*** - ***Analyst***

Is there any other potential ways you could secure reimbursement or a higher level of reimbursement, I should say?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

Well, the publication is a key factor in securing reimbursement, but clearly, it's not the only factor. We have quite a large number of initiatives that are ongoing in our seven target markets for reimbursement, and the publication plays a role in all of those seven markets.

But we also have local data being generated. We have physician advocates in each of the markets that are working with their local reimbursement authorities to facilitate interim and ultimately long-term reimbursement, so it's a multi-front, multi-faceted effort.

David Nierengarten - ***Wedbush*** - ***Analyst***

I take it after publication there would still be some time for application for reimbursement and such. Is that fair, and do you have a timing for how long that might take between publication and reimbursement or a higher level of reimbursement?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

You know, I'd say that that's a fair estimate, and the timeline is not statutory --

David Nierengarten - ***Wedbush*** - ***Analyst***

Okay.

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

-- so it really is hard to speculate on it.

David Nierengarten - ***Wedbush*** - ***Analyst***

Okay, thanks.

Operator

I'm showing no further audio questions in queue.

Doug Sherk - ***Delcath Systems Inc.*** - ***IR Contact, EVC Group***

Eamonn, we have a question from the webcast participants.

In terms of the ODAC panel review, can you discuss a doctor's participation in the EAP program; the impact of the ODAC panel review on a doctor's willingness to participate in the EAP program?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

Well, thanks for the question.

The ODAC panel review has initiated quite a passionate and, if not, visceral response from our EAP clinical sites in that they felt that the ODAC got it wrong, and they are actively enrolling patients into the EAP, and as I mentioned during the prepared remarks, there are currently five patients that are scheduled for treatment in the EAP, five additional patients. We'd expect that to continue.

Doug Sherk - ***Delcath Systems Inc.*** - ***IR Contact, EVC Group***

Okay, another question from the webcast participants is can you provide an update on the current plans for commercialization in Australia and New Zealand?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

We are working with a distributor in Australia and New Zealand who is doing a market feasibility study that is scheduled to be completed by the end of the calendar year. They're a subsidiary of a very large, well-known company that we're not at liberty to name yet, but they're well into their feasibility plans for Australia and New Zealand. We're hoping that they'll come online either late this year or early next year.

Operator

Mary Ellen Kay, Aegis Capital Corp.

Mary Ellen Kay - ***Aegis Capital Corp.*** - ***Analyst***

On the studies that you're planning on the other types of liver cancer, how are you going to get funding for that?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

Currently, we have approximately $40 million in the bank. The studies are not extremely material this fiscal year, and fundraising activities down the road will be based on facts and circumstances in that time period.

Graham, would you want to add anything to that?

Graham Miao - ***Delcath Systems Inc.*** - ***EVP & CFO***

Yes, I agree.

Mary Ellen Kay - ***Aegis Capital Corp.*** - ***Analyst***

It seems you're fairly short on cash, I mean looking forward, so certainly there is going to have to be some way to raise capital. What are your thoughts on that?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

Well, we are reducing our -- as we previously stated, with $40 million in the bank, we're reducing our burn significantly based on a reduction in the need for expenses associated with ODAC prep and an NDA support. There are a number of avenues for access to financing, including capital markets, as well as revenue generation and partnerships.

Doug Sherk - ***Delcath Systems Inc.*** - ***IR Contact, EVC Group***

Okay, we have a couple of other questions from the webcast participants. First of all, what chemical agent do you plan to use in the HCC trial?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

The decision has been made to utilize melphalan in the HCC trial, and that's been based on our very strong positive signals from our Phase 2 data, as well as the long history of isolated hepatic perfusion with melphalan via the surgical route.

We looked very closely at doxorubicin, and although doxorubicin data is also appealing, melphalan wins out in that doxorubicin is extremely liver toxic, so the dose escalation of doxorubicin is limited by the local toxicity in the liver, where melphalan is not especially liver toxic. The healthy liver tolerates melphalan very, very well, so melphalan is relatively tumor specific in the liver. And, also, it has a very short half-life, where doxorubicin has a very long half-life. And our ability to dose escalate is not limited by the liver; it's limited by our ability to keep the very large concentration or large dose of the drug contained within the liver. So the isolation methodologies we use, including our Gen 2 filter, come into play in a much more tangible way. So melphalan it is for HCC.

Doug Sherk - ***Delcath Systems Inc.*** - ***IR Contact, EVC Group***

Okay, with regard to the ODAC concerns regarding hypotension issues, can you comment, please?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

Yes, the FDA briefing document and ODAC really made this a very large issue, and certainly, we take it seriously, but our characterization of this issue was that it was overemphasized as being a material issue from a clinical perspective.

Certainly, long periods of hypotension are very concerning in that they can lead to organ failure and other very serious conditions.

The hypotensive episodes in our procedure are brief and manageable. Now, the Phase 3 trial did not collect real-time mean arterial pressures, so when FDA connected the dots, if you will, between the very broad data that was collected and they concluded that there were very long periods of hypotension that were of considerable concern. We, in our trials going forward, are going to measure mean arterial pressure very systematically and much shorter time intervals between measurement, which will provide a much clearer picture for FDA to understand that the hypotensive episodes are very brief in duration, they last seconds to a couple of minutes, and are very easily managed by the anesthesiologist and attending physicians to make sure that the patient doesn't suffer any ill effects.

Doug Sherk - ***Delcath Systems Inc.*** - ***IR Contact, EVC Group***

Last question that we have from the webcast participants is what are your thoughts on approval in September if you're able to use data from Europe and the EAP program?

Eamonn Hobbs - ***Delcath Systems Inc.*** - ***President & CEO***

Well, as we said in the prepared remarks, the FDA hasn't told us what they're going to need with regard to approving the Gen 2 filter system, so speculating on what they're going to be needing is probably not a good idea at this time.

In the briefing document, FDA had suggested that not only would additional clinical data be required, but a randomized control trial to demonstrate both safety and efficacy would be required.

When we read that, we felt that that really did not properly characterize what a filter change could and couldn't do in that we don't feel that the filter can play a role in efficacy since the filter is only involved in removing the chemotherapeutic agent after it's done its job in the liver. So regardless of what filter's used and, in fact, even if no filter was used, the liver would see the same treatment dose and will have the same efficacy response.

We had a meeting, an urgent meeting, with the FDA, and the FDA was gracious enough to accommodate that literally the day before ODAC, where we specifically went into details on what we recommended for additional clinical data, and we suggested that we utilize both the U.S. EAP and compassionate use data, as well as the European retrospective and prospective safety data collection. And we ended that meeting with the FDA saying that they would opine and get back to us in due course. So until they do get back to us, we really are in a wait-and-see posture.

So now that the Q&A is over, I'd like to thank everyone for joining us today, and thank you for your interest and your support.

Operator

Ladies and gentlemen, that concludes today's conference. We thank you for your participation. You may now disconnect. Everyone, have a great day.