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): **April 15, 2011 (April 11, 2011)**

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 April 11, 2011, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss the Company's new drug application submission strategy 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.

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: April 15, 2011

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. #4431725
DELCATH SYSTEMS, INC. - CONFERENCE CALL
April 11, 2011, 4:30 PM ET
Chairperson: Doug Sherk (Mgmt.)

Operator: Ladies and gentlemen, thank you for standing by, and welcome to the Delcath Conference Call. During today's presentation, all parties will be placed 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're using speaker equipment, please lift the handset before making your selection. This conference is being recorded today, Monday, April 11th of 2011.

I would now like to turn the conference over to Mr. Doug Sherk of EVC Group. Go ahead, sir.

Doug Sherk: Thank you, Michaela, and good afternoon, everyone. Thank you for joining us today for this conference call and webcast to provide an update on the submission strategy for our new drug application with the FDA. 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. The live webcast of this call is available 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 address the issues raised in the Refuse to File letter from the FDA and the resubmission of the new drug application to the FDA; acceptance for review by the FDA of our NDA application; approval of our NDA by the FDA and corresponding adoption, use and revenue in the United States; CE Mark approval and corresponding adoption, use and revenue in the EEA; the Company's ability to secure regulatory approval of current or future drug delivery systems for new indications; actions by regulatory authorities; the Company's ability to complete the Phase 2 and Phase 3 manuscripts and submit for publication; 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 activity. These factors and others are discussed from time to time in filings with the

SEC, including the Form 10-K for the fiscal year ended December 31, 2010, which was filed on March 8th, 2011. 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 obligations 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 re-queue to ask additional questions.

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

Eamonn Hobbs: Thank you, Doug, and good afternoon, everyone. With me today are Dave McDonald, our Chief Financial Officer; Krishna Kandarpa, our Chief Medical Officer and Executive Vice President of Research and Development; John Purpura, our Executive Vice President of Regulatory and Quality Affairs; and John Blanchette, our Director of Clinical Operations. The primary purpose of our call today is to update you on our new drug application, or NDA, submission strategy for our proprietary chemosaturation system used in the treatment of patients with metastatic melanoma in the liver. In addition, we'll report on the progress of our CE Mark application for the broader indication of delivery of melphalan for all liver cancers, as well as the updated schedule for submitting the data from both the Phase 2 and Phase 3 trials to medical publications.

Let's begin with the NDA submission.

As you know, we submitted our original NDA on December 22nd, 2010, and received a Refusal to File, or RTF, letter from the Food and Drug Administration on February 18th. That letter requested information on a number of items, including manufacturing plant inspection timing, product and sterilization validations, statistical analysis clarification concerning randomization and additional safety information regarding patient hospitalization data in the trial. With respect to the patient hospitalization data, we had previously notified the FDA that we already planned to submit some additional data on patients treated with chemosaturation in our Phase 3 trial in April as part of the 120-day safety update. Based on FDA communications, we believe that more extensive additional safety data as well as further clarification of that data must be in the resubmission in order for FDA to ultimately review the overall risk/benefit profile for the system. We appreciate the clarity FDA has provided to address their concerns and will take this opportunity to rigorously obtain the necessary information and data from the medical records of patients who are enrolled in the completed Phase 1, 2 and 3 clinical trials. At this time there has been no request for additional studies or new data to be

generated. Let me reiterate, the FDA did not request that we conduct nor have they requested since issuing the RTF any new clinical trials related to our application. In order to create the most compelling, clear and complete application possible, we will collect all of the available safety information for all the patients in all three of our clinical trials that used melphalan. We currently estimate that the supplemental monitoring involved in the collection of this additional data will extend our original submission goal of September 30th to the end of the year. We believe the extension in our timeline to collect the additional safety data, perform analyses and communicate with clarity what we believe to be the overall favorable risk/benefit profile is the right course of action to increase the chances for the NDA submission to be accepted and ultimately approved.

With that as a summary, let me now provide a bit more granularity on the process.

After receiving the RTF letter in February, we immediately set out to identify the best resources we could possibly find to help our team understand the FDA's request and develop strategies that would result in a submission accepted for review. We believe we have succeeded in significantly strengthening our team's capabilities. Within two weeks of receiving the RTF, we had retained several additional medical oncology consultants, including both a 16-year veteran of FDA's Oncology Review Division, as well as a senior executive [formerly] with the regulatory department of one of the world's largest oncology pharmaceuticals companies. Working with John Purpura, our EVP of Regulatory and Quality Affairs, this team's first contribution was to develop and submit to the FDA the RTF response, which was an extensive document that provided our proposed plan of action to address each item raised in the RTF letter. In our response, we asked for a meeting to maximize our understanding of the FDA's issues, and we held that meeting last week. As a result of our communications with the agency, we believe we have a clear path to follow in order to respond to the issues raised in the RTF.

Let me start by noting that we believe we can address all the issues the FDA noted in the RTF letter. We further believe that the biggest task to complete for our new NDA submission to be accepted for review is the supplemental monitoring of patient safety data. Our goal with the new submission will be to present the FDA the most clear and compelling safety data available from all three studies that helps improve the agency's understanding of the risks in the context of the patient benefits generated by our system.

To provide you with some information on how we're expanding our submission via supplemental clinical monitoring to provide the additional safety data, I'd like to turn the call over to John Blanchette, Director of Clinical Operations for Delcath. John joined us on January 10th after the original NDA was submitted to the FDA. He joined our Company after

spending nine years as Director of Global Clinical Operations at ImClone Systems which is a subsidiary of Eli Lilly. We believe John is extremely well qualified to lead our clinical operations, as he was involved with more than 30 clinical studies of oncology products at ImClone. John?

John Blanchette: Thank you, Eamonn, and good afternoon, everyone.

Based upon our recent communications with the FDA, we learned that our original plans to clarify our safety data would not completely answer FDA's questions. Instead, our team has determined that the most thorough safety data can be gathered through supplemental clinical monitoring for all three clinical trials. This supplemental clinical monitoring will include the hospitalization data for all patients in the Phase 1, 2 and 3 trials. Our goal in this effort is to collect every piece of patient data so that we are fully prepared to answer any of the agency's questions during the review process. This supplemental hospitalization data was not requested by the FDA as part of the SPA in the Phase 3 trial, and therefore was never prospectively captured on the study's case report forms. Furthermore, the originally approved case report form requires expansion in order to capture the results from the supplemental clinical monitoring. This additional supplemental clinical monitoring we believe will allow us to materially enhance our NDA for resubmission.

The time required to accomplish the resubmission of the NDA is extended for two principal reasons. First, the scope of the task has expanded, both in terms of the amount of data per patient as well as the number of patients for which the data must be collected. When the FDA originally requested additional hospitalization data prior to issuing the RTF, it was in the context of the Phase 3 study. We now believe that to better answer their questions, it is prudent to collect all hospitalization data on all patients in all three studies. The result is that we will be gathering data on 186 patients, which approximately triples the number of patients requiring supplemental monitoring. The second reason is that there are significant logistics issues at the center that enrolled the most patients, the National Cancer Institute (also known as NCI). Of the 186 patients in the three trials, almost 75% of them were treated at the NCI. This creates a logistical challenge, as there are space and human resource limitations issues in terms of how many of our monitors can be accommodated at any one time to review patient records. As a result, we currently estimate it will take a total of up to 15 weeks to complete the supplemental monitoring process. This supplemental monitoring process requires the most time of any component in the development of our NDA and we are pursuing the quickest and most accurate format possible. We plan to monitor other sites concurrently and continue to explore other ways of potentially accelerating the process at the NCI. We currently believe that we will complete the supplemental clinical monitoring in August; then, our team of experts will conduct the analysis of the data. When combined with an update on the status of the patients in the Phase 3 study, the

significant amount of additional data will require that a substantial portion of the existing NDA be re-drafted. We currently estimate that the NDA will be submitted by the end of the year.

Now, let me turn the call back to Eamonn.

Eamonn Hobbs: Thanks, John.

We believe taking this action now and investing the additional time into our submission vastly improves our ability to have the agency accept and ultimately approve our application.

Let me briefly update you on other developments.

We remain confident about receiving CE Mark approval to market the chemosaturation system in Europe. We have continued to have positive dialogues with our Notified Body in the last month, and we believe we remain on track to receive the CE Mark by the end of this quarter. Assuming this remains the case, we would first begin to build inventory of the chemosaturation system and establish the commercialization infrastructure in Europe, including assembling a direct sales organization to cover the countries of Northern Europe and third party distributors to cover the Southern European countries. We believe that these activities will set the stage for the material commercial launch of the chemosaturation system in the European Union in 2012.

Turning to the status of publication of the data from our trials, we currently believe that the article on the neuroendocrine tumor data from the Phase 1 and Phase 2 studies will be completed by the principal investigator and submitted for publication to a prestigious medical journal during the summer. A presentation of this data is currently planned for the Cardiovascular and Interventional Radiology Society of Europe meeting in Munich in mid September. The other arms of the Phase 2 clinical trial are expected to be submitted for publication at a later date. With respect to the publication of data from the Phase 3 trial, the investigators believe that incorporating the additional data being collected for the FDA submission will significantly enhance their article. As such, we expect that following the receipt of the updated data, the article will be finalized and submitted to a top tier journal by the early fall. We currently expect this updated Phase 3 data to be presented at the European Society of Medical Oncology meeting in Stockholm in late September. We will keep you updated as developments occur.

Before we open the call up to questions, I'd like to ask Dave McDonald, our Chief Financial Officer, to provide a brief update on our financial picture.

Dave McDonald: Thanks, Eamonn, and good afternoon, everybody.

From a financial perspective, we don't think that the additional resources required to execute the submission strategy reviewed today will have any material changes to the 2011 projected cash burn. The additional near term regulatory expenses are expected to essentially replace what we had previously intended to spend on US commercialization activities in the second half of the year. To update you on the recent cash usage, our monthly cash burn in the first quarter was approximately $2.6 million, and the cash balance as of March 31 was approximately $39.3 million.

With those opening remarks, Operator, we're ready to take questions.

Operator: Thank you, sir. Ladies and gentlemen, we will now begin the question-and-answer session. As a reminder, if you have questions, 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're using speaker equipment, you will need to lift the handset before making your selection.

Our first question comes from the line of Greg Wade with Wedbush Securities. Please go ahead.

Greg Wade: Good afternoon. Thanks for taking my question.

Eamonn Hobbs: Hey, Greg.

Greg Wade: Hey. I would like to better understand the data points that the FDA is looking for here. Is it survival or hospitalization? Then from an execution perspective, were the patients within this study all consented to a sufficient degree to allow for the reperusal of their medical records? Thanks.

Eamonn Hobbs: Well the second part of your question, they were indeed consented broadly to allow for the supplemental clinical monitoring to collect all the hospitalization data in their charts—in their patient records. The information the FDA has requested is, centers around hospitalization data in order to clarify the safety profile of the procedures. And, you know, to take that a little bit further, what we've learned is part of the issue is that we are a combination product and the hospitalization profile is much more complex than what would be normally submitted in a drug submission in that we have an operative—a multiple operative procedure profile. So we not only have the sequelae to the administration of the drug, we have the impact of the procedures, the operative procedures as well. So that creates a much more complex picture than you'd normally see in a typical drug submission, so that's one of the reasons why the expanded hospitalization data helps to clarify that for the reader of the NDA.

Greg Wade: Okay, I would like to follow up on that. Were patients permitted to be retreated in the Phase 1 and 2 studies? And so is what the agency looking

for, is it more—is the score on acute rehospitalization? If they're coming back six months later to be retreated, obviously they're going to be re-hospitalized. Thanks.

Eamonn Hobbs: Yes, the answer is yes, the Phase 2 trial included multiple procedures. The Phase 1 trial I believe, so, yes, Krishna's nodding that it did. It was a dose-ranging study. The interval between procedures was defined to four to six weeks, so we didn't have patients showing up helter skelter for retreatment. But the side effect profile did potentially overlap with prior treatment, which creates an overlay from treatment to treatment and connecting the dots between which hospitalization was associated with which AE or SAE, is really what we believe the agency is looking to clarify.

Operator: Thank you. And as a reminder, ladies and gentlemen, if you would like to ask a question, please press the star, followed by the one. If you're using speaker equipment, it will be necessary to pick up your handset before pressing the star key.

And we have a question from the line of Jason Mills with Canaccord Genuity. Please go ahead.

Jamar Ismail: Hi, this is Jamar Ismail calling in for Jason.

Eamonn Hobbs: Hey there. How are you?

Jamar Ismail: I'm pretty good. My first question is, are there any unknowns ongoing into the remonitoring, any surprises that could come up?

Eamonn Hobbs: Well, anytime you do supplemental monitoring, you should expect to find additional AEs and potentially SAEs that were not captured in the original study, but in conversations with the PIs, they really don't feel that there's going to be any material difference in the data that's collected with regards to new and different AEs or SAEs that pop out of the woodwork. So we're not anticipating any game-changing surprises.

Jamar Ismail: Okay. Then in terms of timing, especially with most of these being at NCI, what are the potential pitfalls to making the year-end new timeline?

Eamonn Hobbs: Well the NCI is the bottleneck. They've been very gracious to give us the maximum number of slots available for a 15-week period, so we are very thankful for that. But it could go smoother, there is potential that the remonitoring won't take all the 15 weeks but it could indeed run longer. We're taking our best estimate at this time based on certain assumptions and, you know, there is, depending on the monitoring and how it goes that's the item that is least within our control. John Blanchette, do you want to elaborate on that?

John Blanchette: The only thing I would say about the NCI of course is that they have very graciously afforded us the maximum number of seats available. The NCI of course does answer to other sponsor companies so we feel very fortunate that we've been given so many spaces for an extended period of time so that we can quickly execute what has been a meticulously planned out process for remediation.

Operator: Thank you. And we have a follow-up question from the line of Greg Wade with Wedbush Securities. Please go ahead.

Greg Wade: Thanks for taking my follow-up question or two, should I think of another one. Eamonn, with respect to the time that you have now between now and the end of the year for this rehospitalization analyses, I'm curious how much additional overall survival data you might have, and why that is not more of a focus of the agency versus historical performance of these patients versus this rehospitalization rate. Can you give us some sense as to what the agency is thinking also in terms of what is an acceptable benefit/risk result here? And what has the Company seen to this point with respect to acute rehospitalization rates due to perceived side effects from the procedure? Thanks.

Eamonn Hobbs: Well first off, on the tail, we would expect to see a tail because the majority of the patients in the Phase 3 trial were treated in 2009—2008, 2009, so—and we still do have patients alive on the trial, so the tail, if you will, on the Kaplan-Myer curve is certainly going to be in our favor with regards to putting the safety in the proper context versus benefit. It was pretty clear from the RTF and our communications with the agency that they really could not get their arms around defining what the safety profile of this procedure looked like, so one of the, and we believe the major reason for the refusal to file was their inability to, under review, to calculate a risk/benefit ratio because the risk was not clear to them. So, really, the remediation that the supplemental monitoring is going to provide is to clarify the risk profile so that they can do the risk/benefit ratio and we're very optimistic that that risk/benefit ratio will be strongly on the benefit side. So, and did you have another question in there?

Greg Wade: That was really it. When do you think we'll see this sort of more mature Kaplan-Myer curve, survival curve?

Eamonn Hobbs: Well that'll be presented in September at the ESMO meeting.

Greg Wade: Great, thanks.

Operator: And at this time I would like to turn the conference back to management. Please continue.

Eamonn Hobbs: Well thanks, everyone, for participating in today's call. We will report progress as it develops and appreciate your interest and support. All the best. Have a great day.

Operator: Ladies and gentlemen, this does conclude our conference for today. If you would like to listen to a replay of today's conference, please dial 303-590-3030 or 1-800-406-7325, with an access code of 4431725#. We thank you for your participation and you may now disconnect.

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