# 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): **February 25, 2011 (February 22, 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 February 22, 2011, Delcath Systems, Inc. hosted a conference call to discuss recent corporate developments. A copy of the transcript of the conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

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

**Item 9.01. Financial Statements and Exhibits.**

The following exhibit is filed herewith:

(d) Exhibits.

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

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DELCATH SYSTEMS, INC.

Dated: February 25, 2011

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

**EXHIBIT INDEX**

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

# DELCATH SYSTEMS, INC. CONFERENCE CALL
February 22, 2011, 8:30 AM ET
Chairperson: Doug Sherk (Mgmt.)

Operator: Good day, ladies and gentlemen, and thank you for standing by, and welcome to the Delcath 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 at that time, please press the star, followed by the one, on your touch-tone phone, and if you would like to withdraw your question, please press the star, followed by the two. We would like to limit the questions to one, with a follow-up, and then if you have additional questions, you may re-queue. If you're using speaker equipment today, please lift the handset before making your selection. This conference is being recorded today, Tuesday, February 22nd, 2011.

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

Doug Sherk: Thank you, Jill, and good morning, everyone. Thank you for joining us today at this early hour for this call to update our analysts and shareholders about the status of 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. This call is also being webcast live via the Company's website at www.delcath.com, and the call will also be archived on the website.

Before we begin, let me quickly reference the Private Securities Litigation Reform Act of 1995, which provides a Safe Harbor for forward-looking statements made by the Company. Today's call may contain forward-looking statements which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to the Company's ability to successfully complete and resubmit the new drug application to the FDA; acceptance by the FDA of our NDA application; the Company's ability to secure regulatory approval of current or future drug delivery systems in foreign markets; actions by regulatory authorities; changes in the healthcare environment, including reimbur sement 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 Securities and Exchange Commission, including the Form 10-K for the fiscal year ended December 31, 2009, which was filed on February 26, 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 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. Given management's schedule and the market open in approximately one hour, we will conclude today's call at 9:15 a.m. Eastern Time.

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 morning, everyone. Joining me this morning are Dave McDonald, our Chief Financial Officer; John Purpura, our Executive Vice President for Regulatory Affairs and Quality Assurance; and Krishna Kandarpa, our Executive Vice President for R&D and Chief Medical Officer.

Earlier this morning, we issued a press release announcing that Delcath received a refusal to file notification from the FDA for the new drug application, or NDA, for our proprietary chemosaturation system. We received the letter late Friday afternoon, February 18th. While the contents of the letter remain a confidential communication between Delcath and the FDA, we believe the issues cited by the FDA are fully addressable, and based on our current understanding of those issues, we expect to re-file our NDA by the end of the third quarter.

I'd like to point out that, in accordance with application regulations, the FDA has the ability to formally file or refuse to file an application within 60 days of the completion of the submission, which in our case occurred on December 22nd, 2010. Neither the acceptance nor non-acceptance of the NDA filing is a determination of the approvability of the chemosaturation system.

In the letter we received, the FDA requested information involving the timing of manufacturing plant inspection, product and sterilization validations and additional safety information. We already had planned on including the additional safety information with our 120-day safety update in April. In addition, the FDA requested clarification of the presentation of statistical analysis. Our dialogue with the FDA throughout the submission process has been very active and constructive. By the end of today, we will formally request a meeting with the FDA to discuss the issues identified and to confirm our understanding of the remedies required for the filing to be accepted upon resubmission. Our current expectation is to re-submit our NDA by the end of the third quarter.

Meanwhile, the submission of our CE Mark Technical File, the review process for European marketing approval, remains on schedule and we

continue to expect CE Mark approval by mid-year. Our file in Europe is for a Class III device for the use of melphalan to treat all liver cancers, so Europe represents a potentially far broader market compared to the US. Our plan is to initially focus on the six countries that represent 89% of the total EU liver cancer market. We believe that the addressable market opportunity in these six countries just for our Hepatic ChemoSAT system alone is approximately $3 billion. It is important to note that melphalan for injection is commercially available in these six countries, as well as an additional eight countries within the European Union.

I'd like to now turn over the call to Dave McDonald, our CFO, for a few comments. Dave?

David McDonald: Thanks, Eamonn, and good morning, everyone. I'd like to briefly update you on our financial condition. Our balance sheet remains strong, cash and investments were just over $47 million as of December 31st and we remain debt free. Our monthly cash burn rate continues to hover around $2.2 million per month. Now, while we continue to manage our cash position judiciously—we'll defer non-mission critical expenses where possible—we still anticipate the monthly burn rate will rise in the coming quarters. We believe we have sufficient capital to fund our operations, however, through the remainder of 2011 and into next year.

We will prepare for what we anticipate will be a European commercial launch in the second half of this year. We remain optimistic about our opportunity in Europe and will commit the resources required to successfully execute our business plan in this key market. In addition, we'll continue to spend on further research and clinical investments to ultimately seek expansion in the applicability and benefits of our therapy to an expanded number of liver cancer patients.

Now with that, I'd like to turn the call back over to Eamonn. Eamonn?

Eamonn Hobbs: Thanks, Dave. Let me conclude our prepared remarks by saying that although the FDA's decision was certainly disappointing to us, we remain confident about our prospects in the United States. Our management team and Board spent much of the second half of last year formulating the Company's first strategic plan, a plan that we believe will help Delcath become a very successful and profitable company. We look forward to updating you on future calls about how we are executing against this plan.

And with that, Operator, we're ready to take questions.

Operator: Thank you, sir. As a reminder, ladies and gentlemen, if you wish to ask a question, hit star, one on your touch-tone phone now. And as a reminder, please ask only two questions and then re-queue. And this call will be ending promptly at 9:15 Eastern Time.

Our first question comes from the line of Mr. Matthew Pommer with Roth Capital Partners. Go ahead, sir.

Matthew Pommer: Good morning, guys. Thanks for taking the questions.

Eamonn Hobbs: Morning, Matt.

Matthew Pommer: First, Eamonn, let's see. I was wondering if you can help us understand the part about the request for additional statistical analysis clarification. What is the significance of that, and what's involved?

Eamonn Hobbs: Well, without getting into the deep specifics, the clarification they have requested is something we feel we can readily do and provide. It wasn't anything that caused us great alarm and we're confident we can provide the data—the clarification that they're looking for.

Matthew Pommer: So, let's see. And secondly, can you explain how the NDA did not contain the relevant information related to manufacturing plant inspection timing, product sterilization, validations and the additional safety information? And, you know, as a follow-on, maybe if we can just, you know, I guess make it clear that you will not require any additional clinical data before re-submitting your application?

Eamonn Hobbs: Yes. The refusal to file did not ask us to conduct any additional clinical trials. The explanation for all of the above is quite a detailed explanation. The—we felt when we filed our NDA that it was complete and FDA didn't agree with that and asked us for the information that was provided to be supplemented and asked us to look at the information in other ways, via the same data analyzed in different ways. So we don't—outside of the additional safety data, we don't plan on providing any additional data. The additional safety data involves the clinical trial data at a different cut and point in time, which we had planned on filing in our 120-day safety update. So the original NDA had a cut-off date for clinical data of April of 2010; our re-submission will basically add another year, which we believe is strongly in our favor.

Matthew Pommer: Okay, that's helpful. And finally, is there any update you can provide as to the status of the CE Mark application, and is there any effect that you envision from the request made by FDA that in any way could this be requested by the regulators on that side?

Eamonn Hobbs: No, they're completely unrelated. The two systems are markedly different. We are, as you know, regulated as a drug in the United States and our delivery apparatus is regulated as a device in the EU. We don't see any implications for this having an impact on our EU filing in any way, shape or form.

Matthew Pommer: Great. Thanks for taking the questions.

Eamonn Hobbs: Thank you.

Operator: And our next question comes from the line of Brooks West with Craig-Hallum Capital. Go ahead please.

Brooks West: Good morning. Can you hear me?

Eamonn Hobbs: Good morning. Morning, Brooks.

Brooks West: Thanks for taking the question. Eamonn, assuming a re-file by, you know, the end of September, can you walk through the potential timeline then from there to US approval?

Eamonn Hobbs: Well, it's very similar to the one we were just on. Assuming we filed at the end of September, there would be 60 days for the FDA to consider our application for completeness and to hopefully accept the application. We would, again, ask for priority review which would be a six-month PDUFA clock. So let's say six months from the end of September takes us out to the end of March in 2012 for a best case PDUFA date based on a late September filing.

Brooks West: Okay. And then, Dave, just circling back to the cash, can you give us an idea of—you know, you say you're about $2.2 million per month right now—what you expect the ramp to look like as you build towards, you know, European commercialization and, you know, do you feel like you have enough cash to get through that March 2012 date?

David McDonald: Thanks, Brooks. You know, we haven't forecasted what that ramp is going to look like. Certainly, we think we've got cash well into 2012, you know, with, as we've said historically, the policy is we always want a strong balance sheet and always like to maintain adequate cash. So whether we have enough to make it all the way through, I certainly think we do, but I don't think you'll see us drain the tank to empty either. So we'll manage our expenses, as I said, judiciously and continue to put off things that don't make sense that are tied to the US launch until we absolutely need them. So, with that, we're comfortable where the cash position is and, as I said, certainly more than 12 months.

Brooks West: Great. Thanks, guys.

David McDonald: Yup.

Operator: And once again, ladies and gentlemen, if you wish to ask a question, it is star, one on your touch-tone phone now. To ask a question, star, one. And please remember to limit your questions to two. And again, the call will be ending promptly at 9:15 Eastern Time.

And our next question comes from the line of Jason Mills with Canaccord. Go ahead, sir.

Jamar Ismail: Hey, this is Jamar Ismail calling in for Jason. A first question, just wanted to clarify that there's no additional patient efficacy data that's needed?

Eamonn Hobbs: Yes, that's correct. There is no additional patient efficacy data that was requested.

Jamar Ismail: Okay, great. And then, just the second one is on your manufacturing footprint and capabilities. Do you think you—this needs augmentation or, if it does in the FDA's eyes, are you ready to do that?

Eamonn Hobbs: I'm not—could you repeat the question? Sorry.

Jamar Ismail: Just in terms of your manufacturing capabilities, where do you think that is for a US launch and if the FDA needs any changes or—to that, how ready are you to accomplish those?

Eamonn Hobbs: Well, certainly we felt we were ready and continue to feel that we're ready for—to pass a plant inspection. We just passed our ISO certification so we feel comfortable on that. That will not be a gating item for the re-submission.

Jamar Ismail: All right, thanks for answering my questions.

Operator: Thank you, sir. And our next question comes from the line of Greg Wade with Wedbush. Go ahead please.

Greg Wade: Yes, good morning. Can you hear me?

Eamonn Hobbs: Good morning, Greg.

Greg Wade: Good morning. Hey, just a couple of questions. First up, have there been any sterility failures noted with the validation manufacturing that's been done that have led to this attention of the FDA? And then secondly with respect to what the FDA's identified in the filing package decision, how do you think this is going to impact your European filing? Thanks.

Eamonn Hobbs: The—no, there were no sterility failures. The sterility validations were requested in much greater detail. It was really a technical issue and we don't anticipate any gating items with regard to sterilization validation. In fact, the gating item is really the additional safety data with—and the analysis of that per the additional information—additional analysis that the FDA was looking for that will likely be the gating items for our re-submission.

Operator: And our next question comes from the line—actually, there are no additional questions at this time, sir.

Eamonn Hobbs: All right. Well, thank you, Operator, and thank you all for joining us this morning. We continue to believe our chemosaturation system will become an important treatment option for clinicians to use in controlling cancer in the liver. At the same time, we are firmly committed to providing the FDA, as well as regulatory bodies throughout the world, with the information they need to evaluate the system and ultimately approve our application.

We look forward to keeping you updated on our developments and progress. Thank you.

Operator: And, ladies and gentlemen, that does conclude your call today. Thank you for your participation. You may now disconnect.

**END**