

**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): **November 5, 2010 (November 2, 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 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))
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Item 7.01. Regulation FD Disclosure.

On November 2, 2010, Delcath Systems, Inc. (the “Company”) hosted a conference call to discuss financial results for the third fiscal 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.

Item 9.01. Financial Statements and Exhibits.

The following exhibit is furnished 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: November 5, 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. #4377838
DELCATH SYSTEMS, INC.
3rd QUARTER 2010 FINANCIAL RESULTS CONFERENCE CALL
November 2, 2010, 4:30 PM ET
Chairperson: Greg Gin (Mgmt.)

Operator: Good afternoon, ladies and gentlemen. Thank you for standing by. Welcome to the Delcath 3Q '10 Financial Results Conference Call. During today's presentation, all parties will be in a listen-only mode. Following the presentation, the conference will be opened 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, press the star followed by the two. If you are using speaker equipment, please lift the handset before making your selection. This conference is being recorded today, Tuesday, November 2nd, 2010.

I would now like to turn the conference over to Greg Gin. Please go ahead, sir.

Greg Gin: Thank you, Brandy, and good afternoon, everyone. Thank you for joining us today for Delcath Systems' Third Quarter Financial Results Conference Call. A telephone replay of this conference call will be available approximately one hour after the call's conclusion, and will be available for 14 days. Access instructions will be provided by the Operator after the call's conclusion. This call is also being webcast live on the company's website at www.delcath.com, and the call will also be archived on the company's website for one year.

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 its new drug applications 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 regulatory 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.

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, management will begin with its prepared remarks. Following those remarks, the call will be opened up for a live question and answer session. We request that each participant in the Q&A session limit themselves to two questions, and then re-queue to ask additional questions. 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?

Eamonn Hobbs:

Thanks, Greg, and good afternoon, everyone. Joining me this afternoon are Dave McDonald, our Chief Financial Officer, and Kris Kandarpa, our Chief Medical Officer.

The third quarter was a busy and productive period for Delcath. In the last three months, the Delcath team continued to make substantial progress on key initiatives necessary to complete development, and gain regulatory approval for the Delcath system for chemosaturation therapy.

During today's call, in addition to discussing our third quarter financials, we'll update you on regulatory, organizational, and operational advances, including the status of our new drug application, our new supply agreement with Synerx and Bioniche, the status of publication of our Phase III study data, and new additions to our research and development team.

With respect to regulatory developments, I'll begin with the status of our new drug application. Our team continues to prepare the remaining modules of our FDA submission. As many of you know, we submitted module four, consisting of literature-based non-clinical data in late April of this year. The remaining four modules, administrative and labeling, overall summaries, chemistry, manufacturing and controls and clinical are on track to be submitted to the FDA by the end of the year. This process has been greatly aided by provisions in the new agreement we recently concluded with Synerx Pharma and Bioniche Teoranta.

In addition to securing a supply of melphalan from an established market-leading manufacturer, the agreement provides us the right to reference Synerx's approved abbreviated new drug application, or ANDA, for melphalan, and its associated data files and the chemistry manufacturing and control module of our 505(b)(2) NDA application. We expect this will significantly enhance the quality of our own submission.

With respect to timing of the FDA review process, the FDA normally requires up to 60 days from the date of submission of our last module to indicate acceptance of an application, and designation for either 10 month standard or six month priority review. Products determined by the FDA to meet an unmet clinical need are eligible for a priority review designation, and we believe our indication meets this criterion.

For approval in the European Union, we also remain on track to complete our Class III medical device CE mark and ISO 1345 certifications, and submit our technical file by the end of the fourth quarter. Our notified body has begun conducting quality system and facility audits of our manufacturing facility as part of the CE mark review process.

We successfully completed the stage one quality audit in August, and the stage two audit began this week. Assuming this process proceeds as planned, we would also expect an approximate six-month review.

Turning now to the status of submission of our Phase III trial results to a major peer-reviewed medical journal, the trial's principal investigator and his co-investigators are continuing to work on the manuscript. Assuming that submission is accepted early next year, we are optimistic that the trial results will be published sometime by mid-2011.

We also recently concluded our multi-arm Phase II clinical trial for primary and metastatic liver cancer utilizing melphalan. The data are currently being compiled. We intend to include the Phase II trial results in our NDA submission, and expect to release the top line results thereafter. Subsequently, we will seek publication in a peer-reviewed journal.

Turning now to organizational developments, we continued to strengthen our human and intellectual capital with the addition of accomplished professionals to our Board of Directors, Medical Advisory Board or MAB, and Scientific Team. As we mentioned on our last call, Douglas G. Watson, former President and CEO of Novartis Corporation, joined our Board of Directors in July. Doug's distinguished career speaks for itself, and we believe his strong pharmaceutical experience and extensive knowledge of both early stage and large pharmaceutical companies will be beneficial as we transition to full commercialization.

We are also pleased to welcome Dr. Yonson Ku to our MAB. Dr. Ku is Professor and Chairman of the Department of Surgery, Division of Hepatobiliary and Pancreatic Surgery at Kobe University School of Medicine in Japan. We look forward to his guidance in helping to position the use of our technology in the clinical setting in all our potential markets.

Finally, we added considerable research and intellectual property experience by welcoming two outstanding professionals to our research and development, and operations teams. Bill Appling joined us as our

Senior Vice President of Medical Device Research and Development, and Queensbury Facility Operations, while Dr. Dan Johnston joined as our Vice President of Pharmaceutical Research and Development.

Bill has an extensive background managing new product development programs, and is an accomplished inventor with over 31 issued US patents, and 30 pending US patent applications to his credit.

Dr. Johnston was previously Principal Research Scientist in the Translational Medicine Group at Pfizer. Dr. Johnston brings with him strong knowledge among oncology drug development that will be important as we expand our platform with additional indications for our chemosaturation system.

These appointments strengthen our R&D senior leadership team, and we look forward to their contributions.

In addition to these developments, with our successful equity offering in August, we took a step toward securing the financial resources necessary to complete our commercialization plan. For more on that, and a review of our financials for the third quarter, I'll turn the call over to Dave McDonald, our CFO. Dave?

Dave McDonald: Thanks, Eamonn, and good afternoon, everyone. As many of you have seen, we filed our 10-Q reporting our third quarter results earlier today.

I'll begin my comments with the balance sheet, which I'm happy to report remains very strong. Cash and investments at September 30th were approximately \$54.3 million, boosted by \$33.6 million in net proceeds from our successful offering in August. We remain debt free.

As in the second quarter, our cash burn during the third quarter was approximately \$2.2 million per month.

Now turning to the income statement, we reported an operating loss for the three months of \$7.4 million, and please note, approximately \$1.4 million of the operating loss was related to non-cash equity compensation expense.

Research and development expenses for the quarter increased 83% to roughly \$4.3 million, as compared to the third quarter of 2009. And that reflects the build-out of the R&D department since the prior year period, as well as the spending on our FDA and EU submission.

With that brief update, I'll turn the call back to Eamonn.

Eamonn Hobbs: Thanks, Dave. So to summarize, we have made important progress in all areas of our plan to commercialize chemosaturation therapy. We are on track with our FDA filing, we've secured a reliable source of melphalan

from an established manufacturer, we've added significant expertise to our Board of Directors and Medical Advisory Board, added core strength to our R&D and operational capabilities, and obtained the financing to further support our plan. We look forward to updating you again as we proceed.

With that, Operator, we're now ready to take questions.

Operator: Thank you, sir. We will now begin the question and answer session. As a reminder, if you have a question, please press the star followed by the one on your touch-tone phone. If you would like to withdraw your question, press the star followed by the two. If you're using speaker equipment, you'll need to lift your handset before making your selection.

And our first question comes from the line of Jason Mills with Canaccord Genuity. Please go ahead.

Jason Mills: Hi, Eamonn and Dave. Thanks for taking the questions.

Eamonn Hobbs: Hi, Jason.

Jason Mills: How are you?

Eamonn Hobbs: Well. How are you?

Jason Mills: Well, thank you. First question—I'll just ask both questions and then get back in queue. Generally speaking, Eamonn, could you update us on what you see going forward in terms of additional partnerships, and also what you would be targeting as it relates to partnerships in terms of size; what you're seeing in the potential pipeline, et cetera? And then secondly, perhaps give us your updated thoughts on how reimbursement will track post-approval, assuming that comes on time mid-next year or so?

Eamonn Hobbs: Well, on the topic of partnerships, additional partnerships, we really don't have a lot to add since our last call. During the quarter, we continued to have active negotiations with potential partners, especially in China, but, you know, we're still at a loss to be able to predict if and when a deal might come to fruition there.
It's certainly been a very frustrating, long negotiation, but, you know, we still have very interested potential partners on the other side of the table.

With regard to reimbursement, we—as we mentioned in our last call, we're still anticipating that there are existing codes that can be used to allow hospitals to get paid for the procedure as we introduce it commercially, and we are putting plans together, as we mentioned all along, to enable us to very actively pursue dedicated codes if that becomes necessary or advisable.

We are very actively pursuing a reimbursement plan, both in the United States and in the top markets in Europe, so that when we commercialize the product those reimbursements are available to clinicians, and it facilitates uptake.

- Jason Mills: That's helpful. If I might just ask a follow-up on—you mentioned China, so specific to Asia PAC, maybe you could update us on your original partner there, and what may be planned for additional trials coming out of that partnership?
- Eamonn Hobbs: Well, our original partnership is in Taiwan with Chi-Fu , and what we have planned for collaboration with them is to initiate a Phase I trial with doxorubicin for primary liver cancer or HCC. The plans for that are ongoing. Our anticipation is that we'll be starting that trial as soon as it's possible. Our priorities are clearly focused on melphalan and US and European approval, and then after that, the pursuit of doxorubicin for HCC in a Phase I trial.
- So maybe Kris could speak to the details on the proposed Phase I with Chi-Fu.
- Kris Kandarpa: Yes, thank you, Eamonn. As you said, the work progresses in both the development of the filter and the development of protocols with some expert advisors that we have both in Asia and in Europe. And as soon as those are culled out, we expect that we will start the Phase I trials in Asia sometime late to early '12—2012, I think.
- Eamonn Hobbs: So late 2011...?
- Kris Kandarpa: Late, right, 2011, early '12.
- Jason Mills: Okay, great. Thanks, guys. I'll get back in queue.
- Operator: Thank you. And our next question comes from the line of Matthew Pommer with ROTH Capital Partners. Please go ahead.
- Matthew Pommer: Good afternoon, Eamonn, Dave and Kris. How are you guys?
- Eamonn Hobbs: Very well. How are you, Matt?
- Matthew Pommer: Good, good. So the first question surrounds the NDA. So with regard to the Phase II trial results, did you always intend to include the results to supplement the NDA, and is the allowance of the Phase II results part of your SPA?
- Eamonn Hobbs: With regard to the first part of that question, it's a matter of facts and circumstances. The Phase II data, regardless of whether the trial was complete or not, would have had to have been submitted as part of an NDA application just based on all relevant data associated with a

procedure or a new drug application has to be submitted as part of an NDA.

So fortuitously, the Phase II trial timing worked out such that the trial ended prior to the submission, so we're actively buttoning up the Phase II data. It's being compiled as we speak, so that we can include it in the NDA submission, so that—you know—we think that's a positive.

The SPA was specific to the Phase III trial. So the special protocol assessment had to do with the protocol for the Phase III trial, and really does not encompass the—what we would submit in an NDA. Those are sort of different issues altogether.

So, you know, to summarize all that, we consider being able to put a completed dataset from our Phase II trial a positive as part of our NDA submission, and the SPA was limited to—specific to the Phase III.

Matthew Pommer: That's helpful. And maybe as a follow-on, beyond the Phase II, what—you'd mentioned the results are being compiled and also the four additional modules to be submitted. What's still in that queue? And maybe if you could give us a hint as to a little bit better on the fourth quarter timing?

Eamonn Hobbs: Well, you know, there are a lot of moving pieces here, as you can well imagine. The compiling of an NDA, any NDA, is really a tremendous amount of data; a tremendous amount of paperwork. You know, it's often been compared to a tractor trailer load of paper. Of course, all the submissions are all electronic now, so the pallets of paper that used to go in to the FDA are no longer the reality. It's all done electronically.

The—anyone who has been involved in compiling an NDA will tell you that there's a tremendous number of moving parts. And then each and every one of those parts has to be reviewed with numerous reviews to make sure that the quality is up to snuff. And the most important aspect of an NDA is that it's complete, and it's accurate, and that it's right the first time.

With regard to specific day in the fourth quarter, you know, I wouldn't want to venture a guess on that. We're—I can tell you that it's far more important that we put in a quality NDA than an early one. You know, a day or two here or there aren't really the big issue. What's at stake here is that we do it in the highest quality fashion, and make the FDA's job of reviewing it as efficient as possible based on a high-quality application.

Matthew Pommer: Okay. And maybe a question for you, Dave. Can you talk a little bit more about the incremental spend we might expect on new clinical initiatives as we head into 2011 and thereafter? Additionally, could you maybe layer in some comments about the incremental spend and timing as you begin to think about hiring your sales force?

Dave McDonald: Yes, sure, Matt. As we've said, you know, we would expect the monthly burn rate to increase as we get closer to commercialization and look at additional trials. And so, you know, clearly as we get feedback from the FDA and gauging when we think approval is likely to happen, you know, we'll start building those expenses. So I would expect to see expenses rise a little bit here in the fourth quarter and then continuing into the first quarter, but I don't see any monumental shifts—you know—near-term.

Matthew Pommer: And maybe as a follow-on to that specific to the Queensbury facility. Now that it's operational, can you characterize the planned post-approval headcount and manufacturing capacity of the facility, and maybe contrast that with the state of the facility today? And that's it. Thank you.

Eamonn Hobbs: Well, the—as we mentioned in the prepared remarks, the facility is undergoing—this week its phase two audit—quality systems audit for the Class III technical file submission for CE mark approval. So they're quite busy up in Queensbury. We can't manufacture product to any extent until we get approval for a product specification. So until such time as we get approvals and the like, we will keep the manufacturing side of the facility as lean as we can, because there's no advantage to—of building it up.

But on the other hand, the facility also houses the majority of our research and development activities, and they're extremely busy on a number of fronts. So it's a beehive of activity, and the high level strategy is to keep it as efficient as possible. But on the other hand, we can't save our way to success. We've got to staff it appropriately to get the job done, so we're walking that tightrope as best we can.

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

Brooks West: Hi. Can you hear me?

Eamonn Hobbs: Hey, Brooks. How are you?

Brooks West: I'm doing well, thanks. Eamonn, I wanted to press a little bit more on Jason's earlier question on the partnerships. Are you finding in general that those restarted or started over after the data came out at ASCO? Are you finding that the partners are—or potential partners are satisfied with that, or are they waiting for—you know—secondary data to be published? And then any other kind of—you know—major points of interest that you'd care to detail just on business aspects, or what might be some of the major points that you're going over in the partnership negotiations?

Eamonn Hobbs: Well—you know—we've had a number of milestones in our negotiations with potential Asian partners, ASCO being one of them, and the release of data. But something that's very important to keep in mind is that the primary interest of potential Asian partners has centered around HCC, or

primary liver cancer, and, of course, our indication and our data that we've generated with our Phase III trial is associated with melanoma mets to the liver. So you have to, in a way, connect the dots between if it works so well for a melanoma mets, what's the likelihood of it working well for HCC?

Now, we have had some experience in the past with doxorubicin in the United States in an early trial with regard to HCC, so there is some data to work with. But the net-net of all this is we have—as time goes on, we are building up more and more data. We're building up a better case with regard to how well our system works with melphalan for not only melanoma mets, but with the Phase II data we hope to show that it works with other cancers that have metastasized to the liver, as well as hopefully primary liver cancer there. And as we mentioned, we're looking to generate data going forward with our Taiwanese partner with doxorubicin, a completely different drug to melphalan.

So the net-net of all of this is a lot of moving parts with potential partners, a lot of data for them to go over, and also the way in which these different countries would potentially regulate a chemosaturion system, i.e., would it be a device and a new indication for an existing drug, or would it be a completely new drug, or would it be some other combination has also come up and required a lot of diligence on their part as to pro forma-ing a development timeline with regard to the regulatory strategy in each country.

So a very long answer to your short question, but these are—these are complex negotiations, and as time goes on, our—we feel our position gets stronger as we build our data and reduce risk as we move towards both approval and commercialization in the United States and Europe.

Brooks West: Okay, I appreciate that. And then just if you care to update the strategy for Europe or call it global strategy, and any changes there, or maybe any conversations that you might be having with any of the big global players?

Eamonn Hobbs: Well, no changes with regard to strategy in Europe and the United States. Our plans are to go direct in the United States with our own sales force, and to pursue a combination of direct and distributors in the European Union. We are definitely talking to big strategics with regard to potential co-development programs for their proprietary drugs or pipeline drugs that have had limitations imposed on their viability base on systemic toxicity issues that we can—our technology can potentially correct or minimize.

So we're looking at strategic partnerships in the US and Europe to be more on the collaborative product development side, not on the distribution side. We are—we think the best way to generate value for our—for Delcath is to sell directly under our own label and not in partnership with a strategic.

Brooks West: Okay, thanks. I'll jump back in queue.

Operator: Thank you. And at this time, there are no further questions. I would like to turn the call back over to Eamonn Hobbs.

Eamonn Hobbs: Well, thank you. I'm afraid that's all the time we have for today's call. Thank you very much for joining us, and thank you for your interest in Delcath.

Operator: Thank you. Ladies and gentlemen, this concludes the Delcath 3Q '10 Financial Results Conference Call. If you'd like to listen to a replay of today's conference, please dial 303-590-3030, or 1-800-406-7325 followed by a passcode of 4377838. ACT would like to thank you for your participation. You may now disconnect.

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