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 10, 2011 (November 7, 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, 35th Floor, 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 November 7, 2011, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss the Company's financial results for the third fiscal quarter ended September 30, 2011 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: November 10, 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

Thomson StreetEvents℠

Conference Call Transcript

DCTH - Q3 2011 Delcath Systems Inc Earnings Conference Call

Event Date/Time: Nov 07, 2011 / 09:30PM GMT

Nov 07, 2011 / 09:30PM GMT, DCTH - Q3 2011 Delcath Systems Inc Earnings Conference Call

CORPORATE PARTICIPANTS

Doug Sherk
EVC Group - IR

Eamonn Hobbs
Delcath Systems, Inc. - CEO, President, Director

Graham Miao
Delcath Systems, Inc. - EVP, CFO

Kris Kandarpa
Delcath Systems, Inc. - EVP, Research and Development, CMO

CONFERENCE CALL PARTICIPANTS

Matt Dolan
ROTH Capital Partners - Analyst

Rick Elkin
OPCO - Analyst

Jamar Ismail
Canaccord Capital - Analyst

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Delcath Systems, Incorporated, Fiscal Third Quarter Results Conference Call. My name is Ann and I will be your coordinator for this call. As a reminder, this conference is being recorded for replay purposes. At this time, all participants are in listen-only mode.

(Operator Instructions)

We will be facilitating a question and answer session following the presentation. I would now like to turn the presentation over to Doug Sherk. Please proceed, sir

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Doug Sherk - ***EVC Group*** - ***IR***

Thank you, Ann. Good afternoon, everyone. Thank you for joining us today for this conference call and webcast to provide an update on Delcath's corporate progress. A replay of the conference call will be available beginning approximately two hours 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, 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 risks and uncertainties, and actual results could differ materially from those projected in any forward-looking statements.

The 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 in our reports on forms 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 obligations to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made.

Finally, after our opening remarks we will take questions from analysts and institutional investors. To provide them maximum opportunity to ask questions, we'll be limiting each participant to two questions, and encourage you to re-queue to ask additional questions. We appreciate everyone's cooperation with this procedure.

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

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Thanks, Doug. And, good afternoon, everyone. Before we begin our prepared remarks, I'd like to take a few moments to welcome Graham Miao to his first conference call as Delcath's Chief Financial Officer.

Graham joined us in September as part of the planned expansion of our executive management team, and he brings with him a deep background in global financial operations and management, as well as his experience in both established and developmental stage pharmaceutical companies. We're already benefiting from Graham's keen insights, and look forward to his continued guidance as we complete our transition to a fully commercial enterprise.

As part of the management team expansion, we also appointed Dave McDonald to a newly created position of Executive Vice President, Business Development. Dave is now focused exclusively on the strategic development and partnering opportunities for the ChemoSAT system in Europe, as well as the long term expansion of available markets throughout the world.

In addition, we are pleased to have Dave temporarily based in Ireland, where he can provide additional support to the build out of our European operations and commercialization efforts. Dave's contributions as CFO during the past two years have been immense, and his considerable investment banking experience and skills are well-suited to his new and vitally important role.

I'm pleased that both Graham and Dave are joining me on today's call, along with Kris Kandarpa, our Executive Vice President, Research and Development and Chief Medical Officer.

With that, I'll now turn to the business of today's call. Since we last spoke with you, Delcath has made significant progress in several areas, including development of our next generation system ahead of schedule, presentation of updated clinical data at major medical conferences, and development of the human operational and financial resources required for our initial launch in the EU.

In addition to these topics, we'll also discuss our regulatory progress in the United States, and provide an update on our financial position. Of course, after our prepared remarks, we'll take questions.

I'll begin with exciting news from our Research and Development program. I'm very pleased to report that the development program for Generation Two of our ChemoSAT system is progressing significantly ahead of schedule. We now believe that we'll be able to introduce the new system commercially into European markets, pending the CE Mark approval, in the first quarter of 2012.

This accelerated timeline represents a major positive development, not just for our company, but also for patients and physicians because we'll be able to begin our European launch with a product that offers significantly improved filtration efficiency compared to the Generation One system.

In both in vitro and preclinical GLP, or Good Laboratory Practice, testing, the Generation Two system has demonstrated melphalan removal of approximately 98%, as compared to an average of 72% for the first generation system used in our clinical trial. While the Generation One system is a viable commercial product, we believe that the Gen Two system is likely to significantly reduce the potential for side effects on treated patients, especially on the patients' bone marrow.

It is our expectation that this improved safety profile may lead to ChemoSAT procedure being applied to a wider range of patients. Because Gen Two has been shown to filter a much higher percentage of melphalan before it reaches the systemic circulation, another possible benefit of the Gen Two system is the potential to complement other systemic therapies.

We believe this may allow physicians to treat liver disease in conjunction with other systemic therapies, an intriguing possibility that may accelerate adoption of ChemoSAT by the medical oncology community. We recently submitted our application for CE Mark approval for the

Gen Two high efficiency filter to our notified body, and based on recent discussions we believe the Gen Two system is likely to receive CE Mark approval in January of 2012.

As you may recall, in Europe our hepatic ChemoSAT delivery Generation One system has CE Mark approval, with an indication for the intra-arterial administration of chemotherapeutic agent, melphalan hydrochloride, to the liver with additional extracorporeal filtration of the venous blood return. We have applied for and expect to receive this same broad indication for the Generation Two system.

One final note on Gen Two. Because the timetable for Gen Two is substantially ahead of schedule, we have recently made the business decision not to commence our initial commercial launch in the EU with the Gen One system.

We believe it makes much more sense to wait a few extra weeks for the availability of Gen Two. While this means that we expect our initial product launch to occur in early Q1 2012 instead of December 2011, we believe that the substantial patient benefits represented by Gen Two far outweigh the minor delay in our launch.

Turning now to our commercialization plans for Gen Two. During the quarter we also made substantial progress in securing both the physical and human assets necessary for an initial EU commercial launch.

As we announced in August, we are basing our European operations in Galway, Ireland. We have signed a lease for a facility in Galway, and are preparing to receive product for distribution to customers in the EU. This facility will also house our European administrative functions, as well as our marketing, logistics and customer service personnel.

These efforts are supported by a government grant from IDA Ireland, an agency of the Irish government dedicated to attracting foreign investment to the country. The assistance provided by IDA Ireland will help support the hiring and training of the personnel that we anticipate adding in Ireland over the next three years.

We also intend to establish some manufacturing at our Galway location in the future, which we believe will allow us to take advantage of reciprocal regulatory approvals in countries that require that the device be manufactured in the country where it has regulatory approval. Thus far, we have hired eight employees for our European operations. We anticipate adding approximately another 10 to 15 within the next few months.

Supplementing our own marketing and sales organization, which will call on interventional radiologists, we hope to announce shortly the engagement of a contract organization to provide a dedicated medical science liaison team to assist with medical and clinical education of the referring physicians, which are primarily medical oncologists.

This is important because the medical oncologist typically has the greatest influence over how cancer patients are treated, and will provide a push of patients to the pull of the interventional radiologists that will perform the ChemoSAT procedure.

As a reminder, our initial commercial plan for ChemoSAT remains focused on the five largest EU countries, plus the Netherlands and Ireland, which we are designating collectively as the Target Countries. Combined, Target Countries represent approximately 70% of the EU market opportunity.

To properly pursue this opportunity, we are building a specialized marketing, sales and medical education organization consisting of a direct sales force in northern Europe, specialty distributors in southern Europe, supported by a medical science liaison team that will cover all the target countries.

By using multiple sales, medical education and marketing channels, we believe we will be well-positioned to effectively reach both the key referring physician community as well as the hospital-based specialist who will perform procedures using the ChemoSAT system.

Using medical science liaisons focused on referring physicians to complement our direct sales efforts will enable us to reach the medical oncologists who generally have the greatest influence on the treatment methods for cancer patients. The objective is to create clinical awareness and educate medical oncologists throughout the Target Countries about the benefits of using ChemoSAT and who among their liver cancer patients are best suited for ChemoSAT.

To support the medical science liaison educational efforts, we plan to launch a multifaceted and broad general awareness campaign involving the internet, media, and patient advocacy outreach, professional education, medical conferences and advertising.

Another channel will be our direct sales, clinical support teams, and third party distribution network which will allow us to sell to and train the interventional radiologists. We expect that these hospital-based physicians and their support teams will be directly responsible for performing the chemosaturation procedure and the actual purchase of our ChemoSAT system.

We are actively recruiting across Europe and have filled several sales, marketing and administration positions for our European organization. The direct sales force will be focused on Germany, UK, Ireland, and the Netherlands.

We are also in discussions with multiple specialty distributor partners regarding coverage of markets in Spain, France, and Italy. These specialty distributors bring well-established strong relationships with customers that we expect to leverage.

To support the selling effort and to help drive clinical adoption of the ChemoSAT system, we're in the process of establishing an initial launch and training program for select centers in the target countries. These centers will be among the first to perform the procedures in Europe.

Once hospital staff are adequately trained and proficient in the ChemoSAT procedure, these institutions are expected to become part of our European training center program, which will teach best practices to other physicians throughout the EU region. We are currently in advanced negotiations with a number of leading oncology centers.

As a result of the potential release of the Gen Two system in Europe earlier than anticipated, we now expect training of select centers of Europe to begin in January using the generation two system. We believe that initially launching and training with the Gen Two in Europe provides the best platform and opportunity for a successful commercial start in Europe.

As we have previously discussed, part of our global market development strategy is to leverage our CE Mark for the ChemoSAT delivery system in certain foreign markets. In October, we completed the product notification process with the Medicines and Medical Device Safety Authority in New Zealand, where we expect to begin supplying the ChemoSAT system through an authorized distributor in 2012. We have also completed our filing with the Australian Therapeutic Goods Administration, and expect approval in that market by year-end.

New Zealand and Australia are just two of the many markets that require a CE Mark as a prerequisite for local approval, and which we expect to enter over the next few years. We have also filed applications seeking regulatory approval in Hong Kong and Singapore. In the future, we intend to seek regulatory acceptance in other key markets in Asia, such as Japan, Korea and Taiwan, as well as in Canada, Latin America, including Brazil and Argentina, and the Middle East.

Finally, I'd like to briefly update you on our manufacturing operations. During the quarter, we have continued to make significant progress in establishing our manufacturing processes and quality systems. Our Queensbury manufacturing facility is now fully engaged and preparing to scale up the manufacturing process to support our commercialization efforts.

Now, I'd like to turn the call over to Kris Kandarpa, our Chief Medical Officer, to discuss clinical development activities in the third quarter.

Kris Kandarpa - ***Delcath Systems, Inc. - EVP, Research and Development, CMO***

Thank you, Eamonn. The third quarter was a busy period. We presented our clinical data at four medical conferences in Europe, South America and Asia, and held a number of well-attended and successful symposia to better educate physicians on our clinical data.

I'll begin with a review of the clinical data featured at recent medical meetings and the positive reaction by physicians. Please note that all the clinical data I'm about to review was generated from the treatment of patients using the Generation One system.

Updated efficacy data from our Phase III trial of our chemosaturation system was featured in an oral presentation at the European Multi-Disciplinary Cancer Congress, or EMCC meeting, a joint conference of the European Cancer Organization and the European Society for Medical Oncology this last September.

We believe these positive data reconfirm ChemoSAT as a promising treatment option for patients with metastatic melanoma in the liver who currently have few alternatives.

The 12-month update of the primary endpoint of median hepatic progression-free survival showed eight months for patients in the ChemoSAT arm, compared to only 1.6 months in the best alternative care arm. In addition, median overall progression-free survival also showed a positive trend in the ChemoSAT arm.

In addition to the oral presentation, the Phase III trial results were among only four such trials chosen by EMCC to be highlighted at a Best-of-EMCC press conference during the meeting. The timing of the press event provided high profile exposure for chemosaturation at the beginning of the meeting that was evident throughout the event.

Following these presentations, we were encouraged by the strong positive reactions and excitement from prominent physicians in Europe, including comments from the press conference -- during the press conference - from Professor Alexander Eggermont, former President of ECCO, and Director General of the Gustave Roussy Cancer Institute in Paris, who discussed ChemoSAT during a best-of-show panel discussion.

Professor Ulrich Kielholz of the Department of Hematology and Medical Oncology, and Deputy Director of the Charite Comprehensive Cancer Center in Berlin, Germany, also offered positive comments.

In addition, several physicians at EMCC showed interest in conducting research and exploring the potential for the current or future ChemoSAT system to treat various types of liver cancer, including hepatocellular carcinoma, primary liver cancer that is, metastatic breast cancer, neuroendocrine and metastatic colorectal cancer, as well as adjuvant therapy.

We also announced during the quarter top line results from the hepatobiliary, neuroendocrine tumor and metastatic colorectal patient arms in our Phase II clinical trial in unresectable liver cancer. Patients in the hepatobiliary and neuroendocrine arms showed a positive efficacy signal and a safety profile consistent with that of the Phase III melanoma trial.

Detailed results from the neuroendocrine arm of the Phase II trial were presented at EMCC, as well as the Cardiovascular and Interventional Radiology Society of Europe meetings in September.

The data presented at EMCC included follow-up on 20 of 24 patients in this treatment group and showed a 70% overall hepatic response rate, which was the primary endpoint, including one confirmed response and 13 with confirmed partial responses. On an intent to treat basis, the median overall survival in all 24 patients was 30.4 months.

We are very encouraged by these results, given that the currently available treatment for unrespectable neuroendocrine liver mets with response rates are estimated to be at about 5%.

We also announced top line results for the hepatobiliary cohort of the Phase II trial. There were nine patients with tumors of hepatobiliary origin, five hepatocellular carcinoma, or HCC, and four cholangiocarcinomas. HCC is the most common primary cancer of the liver, and approximately 500,000 new cases are diagnosed worldwide annually.

Both groups had positive efficacy signals. The responses were especially encouraging in the HCC cohort, and consisted of confirmed partial response or durable stable disease. The safety profile on the chemosaturation system was again consistent with that previously reported for the Company's Phase III melanoma trial.

The disease control rate and the anti-tumor activity seen in the HCC arm of this Phase II study are very encouraging for primary liver cancer patients who currently face limited treatment options. We believe these results show a strong signal of efficacy, and support our plan to initiate Phase III and Phase IV trials for hepatocellular carcinoma in the second half of 2012.

We also announced top line results of the colorectal arm of the Phase II trial, and our plans to further study potential chemosaturation in treating colorectal patients. While patients in the colorectal arm showed an inconclusive efficacy study, it is important to note that the small number of these very late stage patients had undergone several prior therapies and had factors that prevented optimal melphalan dosing with our chemosaturation system.

We remain optimistic about the potential use of chemosaturation in a well-defined metastatic colorectal patient population based on our own recent in vitro testing, and a clear efficacy signal of a 60% response rate from isolated hepatic profusion with melphalan in 114 patients with colorectal cancer liver mets.

Accordingly, we're planning to initiate a new Phase II trial next year in less advanced stage metastatic colorectal cancer patients. We also expect to commence enrollment in global studies in the second half of 2012 for other tumor types in the liver such as hepatocellular carcinoma, or HCC, using the Generation Two system

Specifically, we're planning for a global randomized HCC Phase III registration study for patients who have failed sorafenib, or Nexavar, versus best alternative care. Also, a global HCC first line randomized Phase IV study comparing chemosaturation directly to sorafenib.

With that update, I'd like to turn this back to Eamonn.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Thank you, Kris. I'd like to now update you on the status of our planned NDA submission to the FDA. In September, we asked the FDA for a pre-NDA meeting so we could update the agency on our submission plans and get their feedback and direction.

As we announced in our October 27th press release, the FDA scheduled that meeting for mid-January 2012. We are looking forward to meeting with the FDA and, upon completion of that meeting, we intend to incorporate their thoughts into the application before submitting our NDA to the Agency.

With respect to where we are in the process, certain tasks have taken longer than we had anticipated. Based on our efforts to date, the good news is that all the data that we believe necessary for the NDA resubmission is available.

The process of gathering the data has been more involved than we had initially expected, and has included the need to migrate all data from our clinical studies to a new database that is FDA Part 21, Part 11 compliant, which is more conducive to FDA analysis than was the database used at the NCI. The new database also includes an extensively expanded case report form that will include all of the additional safety data that was requested by FDA.

Data entry and monitoring at the various clinical trial sites is ongoing. The clinical trial site staff have been very accommodating and incredibly generous with their time. However, the data migration to the new, significantly expanded database and the review and entry of patient records by the clinical site staff is taking longer than we originally expected.

The process we've asked the clinical sites staffs to undertake is extremely intensive and contributes additional burden to their already limited resources. We are deeply appreciative of the clinical staff's efforts.

Based on the new data that has been entered and monitored to date, our team is gaining more and more confidence about the quality and quantity of the additional safety data being collected. At the end of this process, we are confident that we will be able to present to the FDA the additional safety data in the format that they have requested.

Turning to the status of publication of the results from our clinical trials, the investigators have informed us of their plans to finish journal article submissions for both the neuroendocrine tumor data from the Phase II study and the Phase III data.

Their new schedule for submission has been moved to after the new database for each study has been established, monitoring completed, and the database locked in order to allow them to analyze and incorporate the locked data before completing and submitting the various manuscripts. We intend to provide an update when there is further progress from the investigators to report.

Finally, turning to our expanded access program in the United States. Based on earlier than anticipated availability of the Gen Two system, we plan to submit to the FDA an IND, or Investigational New Drug, amendment that among other things, incorporates the Gen Two into our expanded access program. Assuming the FDA approves our IND amendment request, we anticipate initiated the expanded access program in the early part of 2012.

We believe that it is in the best interest of patients to be treated under the program to provide them with the most efficient product available to us, especially if that same product is being used commercially outside the United States.

Now, before we turn the call over to questions, I'd like to ask Graham to provide an update on our financial picture.

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

Thank you, Eamonn, and good afternoon, everybody. I am pleased and honored to be part of the Delcath team and to take on the responsibilities of CFO. Let me begin by providing an update on the Company's financial condition. Our cash balance as of September 30, 2011 was approximately $44.7 million. We have strengthened the balance sheet during the third quarter by adding approximately $23.6 million of net proceeds through the sale of 5 million shares of common stock.

Turning to use of cash. Our average monthly cash burn in the third quarter was about $3.4 million, up from $2.7 million average monthly burn in the second quarter this year. For the fourth quarter, we expect that cash allocated to operating activities will increase slightly, primarily as a result of ongoing preparations for initial commercial launch in Europe, continued activities associated with NDA resubmission and a continued expansion of necessary infrastructure to advance our strategy.

Regarding our cash position, our strategy is to continue to maintain a strong balance sheet. And as a result, we continue to explore all available options for raising capital.

Turning to the income statement. For the three months ended September 30th, 2011, our operating loss was $12.2 million, which included approximately $0.9 million in non-cash stock based compensation expense. This compares to an operating loss for the same period in the prior year of $7.4 million, which included approximately $1.4 million in non-cash stock based compensation expense.

General and administrative, or G&A expenses were $5.7 million for the third quarter of 2011, compared to $3.2 million for the same period in the prior year. The increase in G&A was primarily due to an expansion in staff, as we continue our progress in transitioning from a development stage company to a commercial enterprise and preparations for initial commercialization in Europe.

Research and Development, or R&D expenses were $6.4 million for the third quarter of 2011, compared to $4.3 million for the same period in the prior year. The increase in R&D expenses was primarily due to our expanded research and development activities, and the regulatory expenses related to the preparation of our NDA resubmission for the FDA.

For the nine months ended September 30, 2011, our operating loss was $30.5 million, which included about $3.4 million in non-cash stock based compensation expense. This compares to an operating loss for the nine months ended September 30, 2010 of $21.2 million, which also included approximately $3.9 million in non-cash stock based compensation expense.

G&A expenses were $15.1 million for the nine months ended September 30th, 2011, compared to $9.4 million for the same period in the prior year, driven by similar factors as discussed for the third quarter.

R&D expenses were $15.3 million for the nine months ended September 30th, 2011, compared to $11.8 million during the same period in the prior year for reasons discussed previously.

And with that, I will now turn the call back to our CEO. Eamonn?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Thanks, Graham. To recap, we've had a very productive third quarter. Faster than expected development of our Gen Two system has allowed us to pursue initial commercial launch in Europe with Gen Two in the first quarter of 2012, and potential inclusion in our expanded access program in the US.

Positive clinical data were presented at four conferences during the quarter, and we are working hard to convert interest generated at those meetings into market momentum.

We continue to make progress on resubmission of our NDA, have completed the product registration process in New Zealand, and expect to receive regulatory approval in Australia in the near future. Finally, we're developing clinical programs that could potentially expand the ChemoSAT product platform.

We look forward to keeping you up to date on our progress. Thank you. And with those opening remarks, Operator, we're ready to take questions.

QUESTION AND ANSWER

Operator

(Operator Instructions)

And our first question is from Matt Dolan with Roth Capital Partners. Please proceed.

Matt Dolan - ***ROTH Capital Partners*** - ***Analyst***

Hey, guys. Can you hear me all right?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

We hear you fine, Matt. How are you?

Matt Dolan - ***ROTH Capital Partners*** - ***Analyst***

Good, good. How are you doing? I'm at an airport, so I apologize for the background. For my two questions, maybe we'll start off from the last call, and considering we're closing in here on the potential date for a European launch, can you tell us what your feedback has been for those six to eight target centers in terms of some of the prospective complexities around training and reimbursement, so forth?

Maybe put it another way, what kind of volume per center should we think about here in the first year of launch?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

The response we've been getting from the initial clinical centers has been really excellent. We've gotten a very warm reception with regard to the importance of the ChemoSAT technology, the agreement that this potentially represents an answer to a very large unmet need, and an eagerness to partner with us to move forward in initiating cases and becoming a center of excellence or training center for other hospitals in the EU and other countries.

With regard to reimbursement, as we've discussed in the past, we've really confirmed that reimbursement is a very local issue. It varies significantly from a process perspective from location to location, and sometimes within the country from locality to locality. So, it's very hard to generalize.

We don't feel that reimbursement is going to impede our ability to get the ball rolling in that there are either existing codes that can be used for reimbursement, or there are new technology reimbursement programs to provide interim reimbursement while we pursue ultimate long term reimbursement for a new DRG code, if it becomes necessary on a local basis.

With regard to guidance on revenue ramp, we're not providing guidance on revenue ramp. It's very early. We are working on that right now, and we're very eager to get started. But I wish I could help you with your crystal ball.

Matt Dolan - ***ROTH Capital Partners*** - ***Analyst***

Okay. Fair enough. We'll follow up on that. And then, secondly, on the generation two product, can you tell us how we should view that filter in the US? How does that layer into the regulatory plan in terms of current timing expectations? I think a lot of people assume that you'd be rolling out with the existing device first. So, how does that change what we should view your commercial ramp to look like?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Our plan to integrate the generation two product into the US regulatory process is currently that we have no plans to add the generation two product to the NDA filing. So it would most likely be handled in an NDA supplement post-NDA approval. NDA supplements are relatively short-term turnarounds compared to an NDA.

Again, very hard to forecast FDA timelines, but NDA supplements -- it's very, very typical for NDA supplements to be submitted in a flurry upon de novo NDA approval. And we believe the generation two product could very well fit into an NDA supplement at this time.

Matt Dolan - ***ROTH Capital Partners*** - ***Analyst***

So, how long after do you think you could get that amended product through?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Well, again, it's very hard to predict FDA timelines. It's up to the Agency, ultimately. But an NDA supplement can, FDA-willing, be turned around in a four-month period.

Matt Dolan - ***ROTH Capital Partners*** - ***Analyst***

Okay. Thanks for the time.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Thank you, Matt.

Operator

And our next question comes from Rick Elkin with OPCO. Please proceed.

Rick Elkin - ***OPCO*** - ***Analyst***

Hi, Eamonn. First question, I just want to get your view of the option of debt financing and whether that's an option that's available to you now on realistic and reasonable terms. And I'm not trying to get you to tip your hand on what type of financing you'll do next time. I just want to know if it's an option that's currently available on commercial terms.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Hi, Rick. With regard to debt financing, if you remember at the annual meeting I discussed in the Q&A session debt financing being one of the options that we were looking at.

Rick Elkin - ***OPCO*** - ***Analyst***

Right.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

And that included the convertible market being very open at the time. Subsequent to that, a couple of things have happened. The convertible market is no longer as open as it was. And, two, our market cap has declined significantly, which puts additional burden on the process of qualifying for a convertible type transaction.

Although, personally, I was very open to the concept of a convertible type financing structure as an option for Delcath during the period when that market was really attractive -- terms were very attractive -- and wouldn't count it out if that market condition came about again. I don't think we're really in a position at the current time to consider it a likely option available to us.

Rick Elkin - ***OPCO*** - ***Analyst***

Just in terms of the journal articles and they're going to wait until the lock down of the data from the resubmission to the FDA, what does that mean in terms of the calendar? When do you expect that lock down to occur? And then, what would it be -- a couple of months after that before they'd actually get submitted? It seems like this is just like each time it keeps getting stretched out. But if you could, I'd like to get some idea of when those articles might be submitted?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Yes. I share your desire to have a solid date when those articles will be submitted.

Rick Elkin - ***OPCO*** - ***Analyst***

Or even a range, you know.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

We've been unsuccessful in estimating what the investigators' timeline has been in the past, so I'm hesitant to keep doing it. I've been very consistently inaccurate. We're really not in a position where we can dictate those terms. And the investigators have taken a very logical position in that they've said, look, we want the publications to be based on the best data available. And since you're creating a significantly expanded database, that would constitute the best data available. So, the old database, although it was fine, isn't going to be anywhere near as complete and broad as the new database.

So, they've said, look -- and in parallel they've been very busy writing the manuscripts with blanks in them getting ready to, hopefully, fill in the blanks. I don't want to oversimplify the process. But they haven't been sitting idly by.

So, we're all vigilantly working to get all this done. The first priority is quality. Second priority is timeline. And the only thing we won't sacrifice is quality. We're pushing as hard as we can on timeline because we all want to get this done.

Operator

And our next question is from Jamar Ismail with Canaccord. Please Proceed.

Jamar Ismail - ***Canaccord Capital*** - ***Analyst***
This is Jamar calling in for Jason Mills. Eamonn, I know you don't want to give specific guidance for 2012, but can you give just a little bit more color on what are you thinking in terms of the next tier of centers after the first six to eight?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Well, the first six to eight are going to be a very well-known group of the lead cancer centers in Europe. And we've gotten tremendous interest from the top tier centers, so we're very gratified by that. The next expansion after that is really going to be based on the ability of those six to eight centers to accommodate the training of additional centers.

As soon as these centers are up and running and we've, via proctors, signed off their log book, so to speak, that they're ready to now become trainers themselves, then we have to negotiate with them how much time can they commit to this. They're committing in our arrangement that we're working on with them to a certain amount, but we can't have all their time. So, we're going to be putting them through as quickly as we can.

And what that translates into as far as the number of centers and a timeline is still a work in progress and yet to be negotiated. But, needless to say, the whole game here is to get as many centers trained and competent on performing the procedure as we can do, again, without sacrificing quality. We want to make sure their training is top shelf and that they can become training centers themselves as the second tier, and then the third tier, et cetera, et cetera.

Jamar Ismail - ***Canaccord Capital*** - ***Analyst***

Okay. I can understand that. And my second question is your ASP assumptions the same for the Gen Two as it for the Gen One?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Our what assumptions? Sorry.

Jamar Ismail - ***Canaccord Capital*** - ***Analyst***

ASP.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

We have yet to disclose our list price and any changes to our ASP in our models. We still believe that the ASPs that we've been modeling are conservative and still a useful tool, the best tool we have so far, to use for the Gen Two. But more to follow on that. By our next call, I think, we will have announced our pricing and value proposition strategy.

Operator

And our next question from Rick Elkin with OPCO. Please proceed.

Rick Elkin - ***OPCO*** - ***Analyst***

Eamonn, just to follow up. I understand what you're saying about the journal articles. Can you give us any sort of idea on the lock down of the data? Is there a range of a few months when you expect that to be done?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Certainly, we have ideas. But, again, we're hesitant to bring those timelines to the forefront today because we are subject to a number of variables we don't control. So, the wild cards in our timeline estimates are the amount of time that the clinical sites can devote to our project.

And as I mentioned during the prepared remarks, the sites are being incredibly gracious, and we really appreciate it. But we're not the only mouth to feed at their table. We're competing for resources with a number of other trials that are ongoing.

Rick Elkin - ***OPCO*** - ***Analyst***

Do you need that data to be locked down in order to have your mid-January meeting with the FDA?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

We couldn't have the meeting with the FDA unless we had a very, very solid idea of what the safety data that the Agency requested was going to look like. I mean, that's the purpose of the entire meeting. So, the locking down of the database is not something we would have to have done prior to that meeting because that is the very last step in the process.

To walk you through, first a new database is established. Then we populate the database by migrating the old database over to the new database. Then we add all the new information. And the new information is then monitored along with the entire new database that we created. And then the database is locked, which is the final, final check.

So, the quality of the data, even before data lock, is sufficient to where we can approach the FDA in the pre-NDA meeting. The data lock date and the FDA date are not necessarily together. So, a very long answer to your short question, but it is a lot of moving parts here. We're confident we'll be fully equipped to be able to conduct our pre-NDA meeting. Things are moving along.

Rick Elkin - ***OPCO*** - ***Analyst***

I mean, is there anything you can say about the state of completion of this data collection process? Is it 75% done, 50% done, 30% done, 90% done? I mean, do you have any feel for anything that could give us a little idea of when it might be finished, roughly? I mean, do you expect it to be finished by the middle of '12, or --?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

The problem is we know exactly how much of the data has been input. And we have updates on that on a routine basis. I mean almost daily. The problem is the sites are being able to devote time to the data migration and new data entry on a very lumpy basis. It's based on their other workload.

So, although we know exactly where we are, that doesn't translate into being able to extrapolate to a definite date when we'll be finished because it depends on the sites being able to provide a consistent amount of effort, which they're really not capable of doing.

Rick Elkin - ***OPCO*** - ***Analyst***

I mean, I'm not looking for a definite date. Just, within what quarter you might be finished in. I mean, something?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Well, we're really not prepared to offer that today based on all the issues that I just went through. I mean, I could venture a guess, but I really don't see it as being helpful because the sites really are the biggest variable in our timeline. So, if the sites focus on this issue and we get lucky there where they're able to focus on this issue, the time will be significantly shorter than if they can't focus on this issue.

So, it isn't a situation where I can say by this date we'll definitely be done because the sites have to do a certain amount of work in a certain amount of time.

I want to be very, very careful here in that I don't want to portray the sites as being a problem here, because we are asking them to do things that are very, very burdensome. So, we're very appreciative of all they are doing. And we do understand when they say, we can't work on it today or tomorrow because they've got really good reasons.

It's not that they don't care. It's because they have other pressing needs that they have to attend to. And that's not our call to make. So, we respect that and we're there every day asking for them to pay attention to it, and working with them to make it as painless as possible to get this all completed.

Rick Elkin - ***OPCO*** - ***Analyst***

So, given all that, how confident are you or can you be that this mid-January meeting you'll be ready with everything the FDA wants and able to actually have the meeting when it's scheduled?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

How I can be confident is because the amount of data that we have collected so far would lead me to believe that we'll be very prepared for our pre-NDA meeting.

Rick Elkin - ***OPCO*** - ***Analyst***

So, I mean, if the meeting was tomorrow you could hold it tomorrow basically, or --?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

I don't know the answer to that question. I really don't. And I haven't asked it myself since the meeting isn't tomorrow. But we're very confident we'll be very prepared for the mid-January meeting with the Agency.

Rick Elkin - ***OPCO*** - ***Analyst***

Okay. You can't even give any kind of what quarter you might be finished with this data lock?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

No. Once again, we're back to the sites are going to determine when we're going to finish based on their ability to focus on the project. And to date, we're competing with other projects at the sites in varying degrees. There are 12 clinical sites. And each of them has different variables associated with them.

But the good news is, we're getting there. It's moving along and the quality of the data is making us more and more confident every day.

Rick Elkin - ***OPCO*** - ***Analyst***

I'm certainly not trying to be annoying, but it just leaves people completely up in the air. I mean, you expect it to be finished this year?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

We finish with the -- what part of this?

Rick Elkin - ***OPCO*** - ***Analyst***

The data locking?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Again, data lock is weeks after we are completed at the sites. Data locking is a process that goes through that takes a number of weeks after we're finished at the sites. We're not finished at the sites as of today.

And we can't estimate when we're going to be finished with the sites because that's dependent on the sites making commitments to us that they really are not in a position to commit to. So, they're very enthusiastic; they're working hard on it.

We've asked them for commitments and they've laid out for us that they have other commitments that they have to attend to. They haven't been able to give us a date that I could put into a schedule to provide anyone with a definitive date. It's a negotiation that we're going through at each of the sites on a routine basis.

So, regardless of how many ways you ask me the same question, we're going to get back to we're dependent on the sites. And the sites are doing everything they can do to juggle the resources that they have to move this project along, and it is moving along every day.

Operator

Ladies and gentlemen, due to the time allowed, this concludes today's question and answer session. I would now like to turn the call back to management for closing remarks.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***CEO, President, Director***

Thank you, everyone. We had a very productive third quarter. And we're looking forward to updating you on our fourth quarter progress at our next call.

Thanks, everyone. Have a great holiday season.

Operator

Ladies and gentlemen, we thank you for your participation in today's conference. This concludes the presentation, and you may now disconnect. Have a good day.