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): August 13, 2012 (August 7, 2012)

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 August 7, 2012, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss the Company's financial results for the 2012 second fiscal quarter ended June 30, 2012 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: August 13, 2012

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.
SECOND QUARTER 2012 CORPORATE UPDATE CALL
August 7, 2012, 8:30 ET

Operator: Good day, ladies and gentlemen; thank you for standing by. Welcome to the Delcath Second Quarter 2012 Corporate Update Conference Call. During today's presentation, all parties will be placed in a listen-only mode. Following the presentation, the conference will be open for questions. If you have a question, please press the star, followed by the one, on your touch-tone phone. If you would like to withdraw your question, please press the star, followed by the two. If you're using speaker equipment, please lift the handset before making your selection. This conference is being recorded today, August 7th, 2012.

I would now like to turn the conference over to Doug Sherk. Please go ahead.

Doug Sherk: Thank you, Operator, and good morning, everyone. Thank you for joining us today for this conference call and webcast to provide an update on Delcath's second quarter 2012 results and recent corporate progress. A replay of the conference call will be made available beginning approximately two hours after the conclusion of today's call and it will be available for seven days. The Operator will provide replay details at the conclusion of today's call. 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 provisions of the U.S. 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. Factors that could cause actual results to differ are discussed from time to time in the Company's filings with the SEC, including our annual report on Form 10-K and our reports on Form 10-Q and 8-K. These documents are available on the Investor Relations section of our website and we encourage you to review the materials. The Company has no obligation to publicly update or revise these forward-looking statements to reflect any events or circumstances after the date they are made.

Participating on today's call are Eamonn Hobbs, President and Chief Executive Officer; and Graham Miao, Executive Vice President and Chief Financial Officer. Following their opening remarks we will open the call to questions from analysts and institutional investors. To maximize the time allowed for Q&A, please ask two questions and if you have additional questions, please requeue to ask those additional questions. In advance, we thank you for your cooperation.

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

Eamonn Hobbs: Thanks, Doug, and good morning, everyone.

Since we last spoke with you in May, Delcath has made important progress on a number of fronts. During our second quarter and in recent weeks, we made substantial progress toward completion of our new drug application and are on schedule for submission to the FDA this month, received FDA acceptance of the IND Amendments for use of our Generation 2 filter in our U.S. Expanded Access Program, expanded the total number of leading European cancer centers participating in our CHEMOSAT launch program to 13, recognized our first ever commercial revenues, raised approximately $21 million in net proceeds through a follow-on offering, and strengthened our Board of Directors with the appointment of two Pharma industry veterans. On our call this morning, I'll provide some more detail on these operational highlights and then Graham will review our financial results. Then we'll be happy take your questions.

I'll begin with an update on our NDA submission. I am pleased to report that, as we reported at our annual meeting, we resolved all outstanding safety queries and locked the database on May 25th. After data lock we conducted statistical analysis and began finalizing the various modules that comprise our NDA submission. Our NDA is based on the efficacy and safety data generated from the use of our Generation 1 system in our clinical trials. At the same time, after consultation with a variety of experts, and the FDA, we have agreed to include the addition of the Generation 2 filter in the NDA as a technical change as part of the CMC, or chemistry manufacturing and control, module. We believe it is in the best interest of U.S. patients to accelerate availability of Generation 2 and that this approach represents the fastest regulatory review path for the Generation 2 system. At this juncture many of the components of the NDA have been completed and sent to an outside vendor for final electronic publishing and we expect the remaining few items to be sent to the outside vendor for final electronic publishing this week so we remain on track to file with the FDA, as planned, mid month. We will be requesting priority review for our NDA at the time of filing. Assuming the NDA is accepted, and that priority review is granted, our expected PDUFA date would be in February of next year.

We are pleased by the FDA's acceptance of our amendments to our investigational new drug application, or IND, and our Expanded Access Programs to include the Generation 2 filter. These amendments permit physicians at select U.S. cancer centers to use the Generation 2 system in expanded access and compassionate use cases after they obtain institutional review board, or IRB, approval. Compassionate use cases, with the Generation 2 filter, have already occurred in the U.S. and we

expect the procedures under the EAP will begin at up to six centers this fall. The amendments also permit use of the Generation 2 system in the clinical trials we have planned as part of our clinical development program and it is our intention to use Generation 2 in all upcoming prospective clinical trials.

Turning now to Europe, in the past few months we've continued to execute our launch plans for the Delcath Hepatic CHEMOSAT delivery system. In the first half of this year, we exceeded our initial goal of signing six to eight European cancer treatment and research centers to initial launch and training agreements. We've signed a total of 13 such centers to date and have a presence in all seven of our target markets of Italy, Germany, France, the United Kingdom, Spain, the Netherlands and Ireland. In addition to being the first to offer CHEMOSAT procedures in Europe, some of these centers will eventually serve as initial training locations where EU based physicians can learn treatment best practices. Five of these centers have begun treating patients so far.

It's helpful to understand a bit about the process by which we activate a new center once a training and launch agreement is signed. After the agreement is finalized, the lead physician identifies all members of the center's clinical and technical support team and we schedule training. Training includes didactic instruction, followed by proctored supervision in the first two CHEMOSAT patients. Initially, proctors were solely U.S. based physicians with experience with chemosaturation therapy from our clinical trials, but we have now included proctors from our first EU treatment center, the IEO in Milan, Italy, and they have proctored their first case in Galway, Ireland. Concurrently, the lead physician at the center identifies specific patients who are excellent candidates for the CHEMOSAT procedure and secures patient consent. After the first two treatments are performed, patient progress and clinical team proficiency is evaluated and future cases are scheduled. These future cases can include both repeat treatments of the same patients and initial treatments of new patients. Due to the nature of European holidays being especially frequent in July and August, as expected, the pace of new centers coming online and conducting procedures has slowed somewhat in the last month.

Having said that, we expect two new centers in the U.K. to do their initial CHEMOSAT patients this month, with one already having done so last week. When the clinical teams return from vacation, training will pick up again in September and we expect that most if not all of the currently signed 13 centers will be activated and conducting CHEMOSAT procedures by the end of the year. A total of 16 procedures have been conducted to date in 13 patients with liver dominant metastases from cutaneous and ocular melanoma, gastric cancer, breast cancer and cholangiocarcinoma. We received CE Mark approval for the Generation 2

CHEMOSAT system in April and the first Gen 2 case was performed at the European Institute of Oncology in that same month. Since then, nine of the 16 procedures have been performed using Generation 2 system and Gen 2 is being used exclusively in all European procedures going forward. Doctors performing the procedures have provided positive feedback about the Gen 2 system's performance and the Gen 2 system has reduced the intensive care unit stay for most patients as compared to procedures performed with the Generation 1 filter. In the future, we believe that the Gen 2 system will also help to shorten the interval between treatments and allow for more treatments in patients who are responding. Moving forward, we don't intend to provide specific procedure numbers each quarter, but as we progress we do expect an increase in the number of procedures performed in Europe as the second wave of centers come online this fall and commercial usage expands at the centers trained thus far.

An important element of this ramp is the establishment of suitable reimbursement mechanisms which vary greatly at national and regional levels across our target markets. Currently, initial procedures are being covered by private payment and research funding. We are working on securing interim reimbursement in each of our target markets and expect some of these mechanisms to begin coming online during our fourth quarter. In certain markets we are also adding additional centers as required in order to provide the critical mass needed to support reimbursement applications. It is particularly encouraging that, for instance, in Germany, Europe's largest market, the interim reimbursement process is being actively sponsored and driven by the German Radiology Society; while in the United Kingdom some of the key centers in the area of cutaneous and ocular melanoma have already applied for interim funding. We believe this underscores the positive interest CHEMOSAT is already generating.

The bulk of the year is being spent on laying the foundation of training, reimbursement, patient recruitment and education of the referral network. Since our agreements with initial launch centers include an initial small supply of sample kits, free of charge, we expect that revenue for this year will be heavily weighted to our fourth quarter, with sales driven primarily by the activated centers we have so far and by third party distributors. With agreements with 13 centers in our target markets in place, our priority for the rest of the year is to complete the training process at each center and drive clinical adoption of the therapy in their respective referring networks. Working with Quintiles Commercial Limited, a global leader in fully integrated market access for the oncology marketplace, we've deployed a dedicated team of medical science liaisons in our key target markets. In an effort to stimulate specific patient referrals to the new CHEMOSAT procedure, the MSL team is educating medical

oncologists about the potential benefits that CHEMOSAT could provide their patients. Simultaneously, our internal commercial sales and specialty distributor sales teams continue to promote the therapy directly to the interventional radiologists who ultimately perform the procedure. Between third party MSLs and our internal commercial sales teams, we will have a field force of approximately 20 heads covering the target markets in Europe by the fourth quarter.

While driving adoption within the referring networks of our initial launch centers, we continue to educate physicians throughout Europe on the potential of CHEMOSAT at major medical congresses. This September, we are sponsoring symposia at two major conferences---the Cardiovascular and Interventional Radiology Society of Europe meeting, or CIRSE, in Lisbon, Portugal September 15-19, and the European Society of Medical Oncology meeting, or ESMO, in Vienna, Austria September 28 - October 2---and are planning a series of smaller regional symposia that will begin later this fall.

As commercial procedures are performed, we are working with the clinical teams at our initial centers to initiate a clinical registry by the end of this year. This registry will allow us to collect specific, standardized data from the commercial use of CHEMOSAT which can be used to improve the product and to provide some support for additional regulatory filings. Additionally, we plan to initiate company sponsored trials in the first quarter of 2013, and are evaluating proposals for investigator initiated trials that may augment our long-term Clinical Development Program to expand our clinical data in hepatocellular carcinoma and metastatic colorectal cancer.

Turning now to research and development, we continue to move forward with a CHEMOSAT system for use with Doxorubicin---a chemotherapeutic agent shown to be effective in the treatment of HCC or primary liver cancer. We expect to be able to apply the CE Mark for CHEMOSAT with Doxorubicin this fall. The CE Mark for CHEMOSAT with Doxorubicin would assist in initiating clinical trials in the treatment of HCC in China and Taiwan----which we believe are the primary markets for CHEMOSAT with Doxorubicin.

Also on the R&D front, we have initiated two R&D programs to evaluate a variety of chemotherapeutic agents for use in new CHEMOSAT systems to treat cancers of the lung and brain. These programs involve the development of dedicated isolation catheter systems, unique filters and procedural changes associated with treating lung and brain which have some unique challenges compared to the liver. We are excited about these development programs and will keep you apprised of progress as these programs develop.

Turning now to the regulatory status in Asia/Pac, we expect to have two CHEMOSAT centers in Australia and one in Hong Kong by the end of this year. In Australia we are marketing the system directly on an interim basis while we search for a suitable distributor to drive clinical adoption.

In Argentina, we have selected a distributor who is in the process of submitting the application to register the CHEMOSAT system, which would cover requirements in Chile as well, with approvals expected in 2013. We are targeting specific centers in these markets with affiliations with major U.S. cancer hospitals, which will provide an avenue for international patients from countries where CHEMOSAT is currently an unavailable treatment option. We currently expect regulatory approval of Gen 2 in South Korea and Canada by the end of this year, Singapore in 2013, and Brazil in 2014.

Finally, before turning over the call to Graham I'd like to say a few words about the changes we recently announced on our Board of Directors. We are very pleased to welcome two very distinguished pharmaceutical industry veterans to our Board. Laura Brege and Tasos Konidaris joined us in early July, and bring with them years of healthcare industry experience and financial expertise. Laura joins us from Onyx Pharmaceuticals, where she most recently served as Executive Vice President of Corporate Affairs. Tasos currently serves as Senior Vice President and Chief Financial Officer at Ikaria Inc. Their experience with global product launches and partnership development, together with their track record of increasing shareholder value, will be invaluable assets to us and we look forward to their counsel.

Additionally, we'd like to thank Rob Ladd for his years of service to the Board. Rob was an early champion of the potential of chemosaturation therapy, first as a Delcath investor and later as a member of the Delcath Board of Directors since 2006. Rob played an important role in our achievements to date, and we appreciate his support and guidance over the years.

With that, I'll now turn the call over to Graham Miao for a review of our financial results. Graham?

Graham Miao: Thank you, Eamonn, and good morning, everyone. Let me begin by providing an update on the Company's financial condition.

Our cash balance as of June 30th, 2012 was approximately $29.3 million and includes the $27 million net proceeds raised from the secondary [follow-on] offering in late May and our ongoing at-the-market program. We remain debt free, although as we announced in the first quarter, we

secured a $20 million working capital credit facility with Silicon Valley Bank. This facility provides us with additional financing options to access capital to support our commercialization plan. Our at-the-market equity facility remains in place and currently has approximately $31 million available to us.

Turning to use of cash, our gross cash spend in the second quarter of 2012 was $14.2 million, a decrease from the $14.7 million in the first quarter, but a significant increase compared to the $8.2 million in the same period in the prior year. The sequential quarterly decrease reflects the Company's commitment to effective cost management. The year-over-year increase was primarily driven by the costs of consultant and external vendors related to the NDA submission preparation and the costs associated with staff increases in various functions to support EU commercialization. Average monthly gross spend was $4.7 million, which was in line with our expectations of between $4 million to $5 million a month, and represents a decrease from $4.9 million in the first quarter of 2012. Following the anticipated NDA submission, we expect average monthly cash spend to decrease to between $3 million to $4 million for the fourth quarter of 2012.

Turning to the income statement, during the second quarter, we generated $106,000 in commercial revenue from the sale of CHEMOSAT kits in Europe, a first and significant milestone in the Company's history as we transition from development stage to a commercial enterprise. As we communicated in the past, our EU commercialization strategy will employ a mix of both direct sales channels by our own field force, and indirect sales channels through third party distributors, and while it's still early, we continue to believe that the blended average selling price will be consistent with the price assumptions used in our financial model.

For the quarter ending June 30th, 2012, our operating loss was $15.3 million, which included approximately $1 million in non-cash, stock-based compensation expense. Selling, general, and administrative (or SG&A) expenses were $7.2 million compared to $5.2 million for the prior year. The increase was primarily due to an increase in sales, marketing, operational support, expansion of staff, particularly for the Company's EU commercialization efforts.

Research and development expenses were $8.2 million in the second quarter compared to $5.2 million for the same period in the prior year. The increase was primarily due to costs related to the continued preparation of the NDA submission to the FDA and the training and deployment of third party medical science liaisons in Europe.

Finally, I would like to let our audience know that we will be presenting at both the Wedbush Life Sciences Conference in New York City on August 14th, and at the Canaccord Growth Stock Conference in Boston on August 15th.

With that, we are 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, please press the star, followed by the two. If you're using speaker equipment, you will need to lift the handset before making your selection. We ask that you limit yourself to one question and one follow-up question and re-queue for additional questions.

And our first question comes from the line of Matt Dolan with Roth Capital Partners. Please go ahead.

Matt Dolan: Hey, guys. Good morning.

Eamonn Hobbs: Good morning.

Graham Miao: Good morning.

Matt Dolan: First question is on the U.S. regulatory side. Obviously, you have a big milestone coming in the next week so we have two points of clarification. I know you anticipate the PDUFA date to be in February, what are you expecting now for a panel to be convened? And the second part is around Gen 2, the ability to submit that device as a technical change, I believe was your best case scenario, so can you just kind of walk us through the genesis of that nod, so to speak, from the FDA and your confidence level that that'll be fully included in the NDA? Thanks.

Eamonn Hobbs: Well, if we have an ODAC panel, which we will be informed of when the FDA accepts our NDA and issues the PDUFA date, if they grant us priority review of six months that would put our PDUFA date in February and our best guess at an ODAC would be in early December. There currently is a tentative scheduling I believe on December 3rd and 4th for an ODAC panel, and that would put us approximately in the right time frame for a February PDUFA date.

With regard to your question regarding the inclusion of Gen 2 in the NDA, we — first, I think it's important to understand that Gen 2 is a refined Gen 1 filter, so there is a, we believe, a very strong argument that Gen 2 is a technical change that does not impact the efficacy of the procedure because the filter is involved after the liver is treated to remove

chemotherapy from the blood. And after consultation with numerous external consultants on both the device side and the drug side, and the submission and acceptance of our IND amendments to allow us to use Gen 2 in the U.S.A., we got into a considered discussion with the FDA and FDA informed us that it was acceptable for us to include Gen 2 in our NDA as a technical change as part of our CMC module. So we feel hopeful that this will produce the shortest time to review and approval in the United States and are very pleased with the way that it all evolved and worked out.

Matt Dolan: All right. Well, that's great to hear. And then the second question's on Europe. Obviously the number of centers are tracking ahead of schedule, I think on the last call you indicated that you expect the number of centers to be added next year should be a multiple of the 2012 number. Is there anything you can give us at this point in time to help us hone in on that target, either on a center or a utilization per center basis?

Eamonn Hobbs: I'm afraid, Matt, it's still very early to really drill it all down to a formula. There's a couple of things that is important to note about our commercial roll-out program in Europe. The first is, we are definitely ahead of schedule, having 13 now, and we do plan to add additional — some additional centers for critical mass purposes to support individual reimbursement, individual country or regional reimbursement. But our plan is more to go deep than to go broad. So in our centers that we have established our 13 our goal by the end of the year is to get them doing as many as cases as we can rather than get every major cancer center in Europe doing just a few cases. The ultimate market we believe in Europe is approximately 170 major cancer centers spread across our seven target markets and we're going to feel our way as far as the best return on investment balancing going deep and going broad. So we know from our experience in the United States and already from our initial experience in Europe that cancer patients will travel to get treatment. We've already had a patient from Spain fly to Milan to receive treatment because the local Spanish center was not up and running yet. So there's going to be a balance between how deep our centers go in producing cases versus adding a new center and incremental cases above that.

Operator: Thank you. Our next question comes from the line of Jason Mills with Canaccord Genuity. Please go ahead.

Jason Mills: Good morning, Eamonn and Graham.

Eamonn Hobbs: Good morning, Jason. How are you?

Jason Mills: Well, thank you. Congratulations on the update. And just sticking with Europe, Eamonn, for a little bit, would love to hear some early statistics, if

you have them, from your Quintiles relationship, specifically generating the leads. You've exceeded expectations in the number of centers you're in, obviously that's great, but the end game is to get the patients through those centers, so have you seen any early successes or any early data that you could point to that would give us some insight into how the referral stream is going in Europe?

Eamonn Hobbs: Well, you're absolutely right. I mean, we totally agree that the name of the game is driving patients through established centers, and really we have yet to see the fruit of the MSL network because the centers are really just getting established. So as we walk through all the bits and pieces, all the sequence of events that have to happen to get a center up and running, and unfortunately it's not a short process on a timeline, it's not tremendously complex but it's very hard to accelerate it. So we're just now getting to the point where the MSL can start to generate referrals from the catchment area of a center such as the IEO in Milan and Gustave Roussy in Paris and JWG in Frankfurt to be able to drive patients in there. Of course, we're further handicapped to this during the summer months. Because frankly you don't want to get sick in Europe during August because the clinicians are not home; they're all out taking their holidays. So we expect on our next call to be able to point to some success stories of being able to drive patients through from the MSL push.

Jason Mills: Okay, that's helpful. And just on the pricing side, congrats on your first commercial revenue. I know it's early, but do you have any reason to believe that the ASP is any different, higher or lower than what you had predicted in the past, and maybe if you could give us an updated thought on that?

Eamonn Hobbs: We're pleased with the early results on the average selling price so far and it's extraordinarily early so everything we are looking at we're trying to take with a grain of salt. But so far so good. We're tracking slightly above the average $15,000 price that we use in our modeling, which is a blend of direct and indirect sales in Europe. So the orders we received so far and the orders that are in the queue from additional centers are trending towards an average selling price that would give us more comfort that $15,000 was an appropriate number in our model. So, so far so good.

Jason Mills: That's wonderful. One U.S. question and I'll get back in queue. If the FDA decides not to give you priority review, maybe so that we can just in our minds ascertain a worst case scenario, for a lack of a better term, what would that timeline look like in your mind?

Eamonn Hobbs: Well a standard review would be 10 months, so it'll be four months from February.

Jason Mills: Okay. So we're talking midyear…

Eamonn Hobbs: Yes, exactly.

Jason Mills: Not a huge difference. Okay, I'll get back in queue, guys. Thanks.

Operator: Ladies and gentlemen, if there are any additional questions, please press the star, followed by the one at this time. As a reminder, if you're using speaker equipment, you will need to lift the handset before making your selection.

And I am showing no further questions at this time. I would like to turn the call back to management for any closing remarks.

Eamonn Hobbs: Thank you, Operator. I'd like to thank everyone for participating in today's call. We look forward to seeing you next week at the Wedbush and Canaccord conferences, as well as updating you on our progress in early November. Have a great day.

Operator: Ladies and gentlemen, this does conclude today's conference call. If you'd like to listen to a replay of today's conference, please dial 1-800-406-7325 or 303-590-3030, and enter access code of 4548817. Thank you for your participation and have a good day.

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