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): **March 14, 2012 (March 9, 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 March 9, 2012, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss the Company's financial results for the year ended December 31, 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: March 14, 2012

By: /s/ Barbra C. Keck
Name: Barbra C. Keck
Title: Vice President, Controller

EXHIBIT INDEX

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

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

DCTH - Q4 2011 Delcath Systems, Inc. Earnings Conference Call

EVENT DATE/TIME: MARCH 09, 2012 / 03:00PM GMT

CORPORATE PARTICIPANTS

Bob Jones *EVC Group - IR*

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

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

CONFERENCE CALL PARTICIPANTS

Edward Nash *Cowen & Company - Analyst*

Jason Mills *Canaccord Genuity - Analyst*

Matt Dolan *Roth Capital Markets - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the fourth-quarter 2011 Delcath Systems Inc. earnings conference call. My name is Jeff and I will be your coordinator for today. At this time, all participants are in a listen-only mode. Later we will conduct a question-and-answer session. (Operator Instructions). As a reminder, this conference is being recorded for replay purposes.

I would now like to turn the conference over to your host for today, Mr. Bob Jones with EVC Group. You have the floor, sir.

Bob Jones - ***EVC Group*** - ***IR***

Good morning, everyone. Thank you for joining us today for this conference call and webcast to provide an update on Delcath's 2011 results and recent 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. A 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 would 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 risk 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 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 obligation to publicly update or revise these forward-looking statements to reflect the 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 allotted to Q&A, we will ask that you limit questions to two and encourage you to requeue to ask any additional questions. We have allotted one hour for today's call and appreciate everyone's cooperation with this procedure.

With that, I would now like to turn the call over to Eamonn.

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

Thanks and good morning, everyone. In 2011, Delcath made progress on several fronts including positive steps towards our goal of realizing the commercial potential of our chemosaturation saturation system in Europe. Since receipt of our CE Mark for our Hepatic CHEMOSAT delivery system in April of 2011, we have been laying the foundation for the launch of the product in Europe this year. Considerable effort has been put into establishing commercial operations in Europe and the formation of the institutional and professional relationships we will need not only to launch CHEMOSAT but to drive its clinical adoption in 2012 and beyond.

During the first few weeks of 2012, these efforts are beginning to produce tangible results. Among the significant milestones we have achieved are execution of our first three initial launch and training agreements with leading cancer treatment and research centers in Europe; performance of the first CHEMOSAT treatments outside of a clinical trial setting. These treatments took place at the European Institute of Oncology and the J. W. Goethe University.

Expansion of our 2012 addressable markets for the CHEMOSAT system with regulatory approvals in Australia and New Zealand; establishment of our European commercial and manufacturing operations headquartered in Galway, Ireland; continued progress in ongoing preparation for our expected submission of our new drug application with the FDA; submission of CE Mark amendment for our Generation 2 CHEMOSAT system; and expansion of our leadership team with the addition of several highly accomplished and experienced individuals to our executive management team, Board of Directors, and Medical Advisory Board--adding the management talent and human capital required to execute on our future plans.

I will begin with an overview of the progress recently made on our rollout plan for Europe. As I mentioned earlier, we have secured agreements with three leading cancer treatment and research centers in Europe to launch our CHEMOSAT system. These centers along with others we expect to announce in the coming months will be among the first in Europe to offer the CHEMOSAT procedures and will serve as initial training locations where EU-based physicians can learn best practices and the benefits of the CHEMOSAT procedure.

We are supporting the training of these centers with a comprehensive instructional program that includes proctoring by experienced US physicians who participated in our clinical trials. Thus far, training has been completed at the European Institute of Oncology, IEO in Milan, Italy, and at the J. W. Goethe University Hospital in Frankfurt, Germany. And we expect to begin training at Schleswig-Holstein University Hospital in Kiel, Germany next month.

As we have announced, the centers in Milan and Frankfurt have begun treating patients. These treatments not only represent the first CHEMOSAT procedures performed in Europe, but also the first procedures conducted outside of a clinical research protocol, an important milestone that marks the beginning of the commercial availability of CHEMOSAT as a treatment for cancers in the liver. Treatments included patients with metastases from breast and gastric cancers in addition to cutaneous and ocular melanoma, which speaks to the potential broad application of CHEMOSAT in the EU.

Early reports from the training physicians are that the patients did well and some repeat treatments have already been scheduled. The enthusiasm some of our early launch centers have for the procedure was reflected at a press conference held by the IEO in Milan, Italy recently to announce the opening of their melanoma center. Hosted by Dr. Umberto Veronesi, Founder of the IEO, and Dr. Alessandro Testori, Director of IEO's division of melanoma and skin muscle sarcoma, the event highlighted the IEO's role as the first cancer center in Europe to offer CHEMOSAT to its patients. We were pleased to participate and support the event with the IEO, which generated a very favorable response from the Italian media.

The procedures at both the IEO and Frankfurt were conducted with the Generation one version of the CHEMOSAT system while our CE Mark amendment for our Generation 2 system undergoes a review by the Notified Body. We will continue our rollout of CHEMOSAT training programs in the EU with Gen 1 while working with the Notified Body to complete the review and obtain CE Marking for Gen 2.

Turning now to the status of our European rollout, in addition to the three training and launch centers already signed, we are working on signing up more and expect to announce agreements with additional centers in the coming months. It is important to note that the patients treated so far include one recent case from outside of Italy who traveled to be treated at the IEO. We have also been informed that other cross-border self-paying patients are being evaluated for treatment at the JWG in Frankfurt. We are encouraged by the initial cases being considered thus far and believe it is indicative of the role these centers can play driving adoption of new cancer treatments.

Our plan is to establish six to eight such centers including those established so far in the first half of this year across the target markets of Germany, United Kingdom, France, the Netherlands, Italy, Spain, and Ireland. These centers will provide a platform to develop a European base of expertise to help drive adoption of the CHEMOSAT system. Once teams at these centers are sufficiently proficient in the procedure, we expect these institutions in turn will train other European cancer centers throughout the region.

To expand from this base, we continue to execute on our two-pronged commercialization strategy. The build out of our direct sales force for the Northern European markets of the United Kingdom, Ireland, Germany, and the Netherlands is proceeding. To address the Southern European markets of France, Italy, and Spain, we have hired our distribution management staff and have begun the process of identifying and reviewing potential third-party distribution parties to cover the region.

As we announced this morning, we have also formally engaged Quintiles Commercial Limited, a global leader in fully integrated market access services with extensive expertise in the oncology market place who will provide medical science liaisons or MSLs field force to educate medical oncologists about the potential benefits that CHEMOSAT can provide their patients in these seven target markets.

Let's turn now to our regulatory affairs and international markets. We have received regulatory clearance to sell CHEMOSAT in New Zealand and in February, announced that we received approval in Australia. We expect to begin supplying the CHEMOSAT system in these markets through an authorized third-party distributor in the second half of 2012. New Zealand and Australia are just two examples of the many markets that require a CE Mark as a prerequisite for local approval and we expect to enter over the next few years.

We have also filed applications seeking regulatory approval in Hong Kong, South Korea, and Singapore, and we intend to seek regulatory acceptance in other key markets in Asia such as China, Japan, Taiwan, as well as in Canada, Latin America including Brazil and Argentina, and the Middle East. We have hired management staff to develop our distribution network to cover these regions.

I will turn now to the submission of our NDA to the FDA. On January 12, 2012, we held a pre-NDA meeting with the FDA to discuss our NDA submission and provide an update on the items identified in the RTF the FDA issued last year. Based on the meeting and FDA correspondence received in response to our meeting request and the briefing packet we submitted, we are satisfied with the responses we received from the FDA to certain questions we had regarding the NDA submission. Accordingly, we will continue with the preparation of our NDA submission as planned and expect to make this submission by the end of the second quarter. We feel good about the process we have made and we believe our NDA submission is on the right track.

Turning to our clinical development program, we have a lot planned for the second half of this year. We intend to pursue four new clinical trials, two in metastatic colorectal cancer and two in hepatocellular carcinoma, also called HCC or primary liver cancer, which include a United States registration trial in each of these two disease states.

In addition, we are currently developing a CHEMOSAT system with the chemotherapeutic agent doxorubicin and in conjunction with strategic partners intend to evaluate it in the treatment of HCC in a new clinical trial in China and Taiwan. We also intend to evaluate a variety of chemotherapeutic agents for use in our system to treat other organs and body regions.

Finally, I would like to say a few words about the strength and depth of leadership talent we have added to the Delcath team over the past year. Additions have included several individuals with significant pharmaceutical and commercialization experience who are already aiding our commercial transition and helping us to position for future growth.

Chris Houchins, Senior Vice President Clinical and Medical Affairs; Harold Mapes, EVP, Global Operations; the appointment of Gabriel Leung to the Delcath Board of Directors; the appointment of Gregory Gores, M.D. to the Delcath Medical Advisory Board; and Graham Miao, our CFO, whom you already know and to whom I will now turn over the call for a review of our financial results.

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

Thank you, Eamonn, and a good morning, everybody. Let me begin by providing an update on the Company's financial condition. Our cash balance as of December 31, 2011 was approximately $31 million. In addition as part of our effort to strengthen our balance sheet, we put in place an at-the-market, or ATM offering financing program in late December of last year to sell up to approximately $40 million in shares of the Company's common stock from time to time. Financing under this program is at our disposal and allows us access to capital. In our 10-K, we reported the program has worked well for us so far. We believe we have adequate access to capital to fund our ongoing EU commercialization and business operations.

Turning to use of cash, our total cash spend in 2011 was approximately $40 million. In the fourth quarter of last year, the average monthly cash spend was about $4.6 million, up from $3.4 million average monthly spend in the third quarter of 2011. The sequential increase was mainly driven by costs associated with the NDA submission as well as staff increase.

Going forward for 2012 on a full-year basis, we expect average monthly cash expenses to be approximately $4 to $5 million to continue to support our EU commercialization activities, NDA submission activities and preparations for initiating new clinical programs. We anticipate generating initial revenues in the second half of the year, which will help offset cash expenditures.

Turning to the income statement, for the year ended December 31, 2011, our operating loss was $46.5 million, which included approximately $4.3 million in non-cash stock-based compensation expense. G&A expenses were $21.3 million compared to $13.2 million for 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.

Research and development expenses were $25.2 million in 2011 compared to $17.6 million in the prior year. The increase was primarily due to our expanded research and development activities and the regulatory expenses related to the preparation of our NDA submission to the FDA.

With that, operator, we are ready to take questions.

QUESTION AND ANSWER

Operator

(Operator Instructions). Edward Nash, Cowen and Company.

Edward Nash - ***Cowen & Company*** - ***Analyst***

Great, thanks very much, guys, for taking my question. It sounds like you guys have achieved a lot this past quarter, so congratulations. I wanted to just get some color on can you give me an idea of how many patients to date have actually undergone the procedure now in Europe? And second part to that is also just how long is it taking the teams from the US to actually train a physician in Europe for the procedure?

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

Ed, we have a total of six patients that have had procedures in Europe, four at the Institute of European Oncology in Milan and two at Johan Wolfgang Goethe University in Frankfurt.

The training program is approximately two days. There is a day of didactic training, full-day of didactic training followed by a day of cases. There is some flexibility at the Institute of European Oncology. We spent an extra day going over a few things after the first day of cases.

At the University of Frankfurt, it was just a two-day program, so a day of training and a day of doing the cases and they had two cases completed by shortly after lunch. So, typical German efficiency.

Edward Nash - ***Cowen & Company*** - ***Analyst***
So overall, the learning curve is actually very, very low for these types of procedures? I assume that physicians seem to catch on very quickly.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***President and CEO***
They do, they do. The techniques that are employed in catheter placement are very standard for interventional radiologists. The post-op patient care for any myelosuppression is very standard for medical oncologists. So really the training centers around making sure every one of the specialties knows their role and understands what's going to be coming at them and they are very well skilled to handle it.

Edward Nash - ***Cowen & Company*** - ***Analyst***

Okay, just one more question and I'll jump back in the queue. With regard to the US resubmission, has all of the data from the NCI now been moved over into your system? I know that that was -- I know that getting access was an issue and you had to work by their hours and stuff. I know you guys were wanting to get all of that in-house so that you could manipulate the data and be able to cut and crosscheck as you needed for the FDA. So I'm just curious if that is all then now in the system.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***President and CEO***
Yes, all the data has been migrated and we are in the stages of edit checks and any queries the edit checks bring up resolution, so we are well along. Clearly there are a lot of moving parts in and NDA but we feel good about the probability of being able to file prior to the end of Q2.

Edward Nash - ***Cowen & Company*** - ***Analyst***
Great, thank you.

Operator

Jason Mills, Canaccord Genuity.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***
Thank you very much. Good morning, Eamonn and Graham. I wanted to ask just for more color. Eamonn, on Europe and you've got a really good initial foothold in three centers, could you talk about not only the next sort of nine months but over the next couple of years, in the past you've talked about a total opportunity in terms of centers and I think you've even talked about the overall opportunity in terms of revenue per center, which make this a relatively large market opportunity.

But talk about conservative estimates in terms of your penetration in terms of number of centers and maybe as we think about building more granular revenue models, the sort of patient flow and how that will trend over the next year to year and a half in Europe?

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

Well, to provide more color on the EU, we believe the market is comprised of over 55,000 patients with melanoma, NET, colorectal, and hepatocellular carcinoma or primary liver cancer. The biggest group there would be the colorectal. And as you can see from the first patients done, we are seeing clinicians think way beyond melanoma.

We had anticipated when we introduced the procedure to -- especially the first centers in Europe that they would start out -- cut their teeth if you will with melanoma patients, where we have the greatest amount of data and then migrate to neuroendocrine and HCC, where our Phase II trial data is strongest.

But what has happened at both centers where we have conducted cases so far and has happened independently is they have come to the conclusion that there is broad applicability to virtually any type of cancer in the liver and hence why we have done a gastric cancer patient, which I believe was our first, and a breast cancer mets patient. And they are continuing to look at things well beyond melanoma. So I think we're getting past that.

We also have -- of the six patients, three were cutaneous melanoma mets to the liver and only one was an ocular melanoma, so we found that very interesting in that our Phase III trial was dominated by ocular melanoma patients for probably a very good reason that ocular melanoma patients really have never had any alternative therapy. And we were interested to see how that would shake out in Europe and now we have a three to one, although it's a very small sample, right out of the gate we are seeing cutaneous melanoma mets to the liver take a lead. So we are very pleased to see that happen as the cutaneous melanoma market is much larger than the ocular melanoma market.

As we look towards the next nine months, it's really very difficult, as I'm sure you can well relate, to provide any sort of viable guidance as to what revenues are going to look like. Since this is our first year and we really don't have any historical data to extrapolate forward, we really are subject to really putting our finger up to the wind.

The good news is we see tremendous enthusiasm, interest, and we are getting more and more confident that we're going to see revenues starting from our first clinical sites, our first training sites in the near future. We have guided to revenues being material in Q3 and Q4 and are getting more and more comfortable of that being the case. But again very, very hard to quantify.

As we move past this year and into next year, we will have the beachhead established with the initial training centers. We will have -- we expect that they are going to have a very pleasant experience from the perspective of attracting self-paying patients from outside of their catchment areas who are going to avail themselves of a CHEMOSAT procedure by getting on an airplane or train or car.

And in fact, we are already starting to see that happen in Milan, where their fourth case was a self-pay patient that flew in for the procedure and did that on their own. We didn't facilitate that and we have been told by the University of Frankfurt that they have also been contacted by American patients who are very interested in the procedure and they're working through scheduling now. So you can well imagine how enthusiastic the hospital administrators are that a new high-tech liver therapy procedure is in their institution and is attracting these high-value patients. So we are very, very pleased with that.

As we move into next year, we expect that there's going to be continued public patient expansion as well as private patient self-pay expansion and these first centers will train many other centers in their respective countries or regions.

The big market driver is likely to be colorectal patients simply because they outnumber all the other patients combined. They represent well over half of the market opportunity in Europe.

So I wish I could give you more definitive numbers, but I think those will evolve as we get some quarters under our belt with revenue.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***
That's very helpful color. Thanks, Eamonn. My follow-up has to do with the US, just following up on the first questioner. In terms of any other color you can give us coming out of the pre-NDA meeting and your confidence level that you have really addressed all the questions that the FDA had initially in the RTF and maybe discuss what your expectations are or aren't for an ODAC panel and also fast-track status once a PDUFA date is set?

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

Well, as I mentioned, we had our pre-NDA meeting on January 12 and 30 days to the day later we got the minutes, so we have sort of tucked that meeting into bed, if you will, and put it in the rearview mirror. Having had a few months of reflection on the meeting, I would have to say we were all very pleased with the meeting. It was a very constructive interaction with the agency. We came out of the meeting with a very good feeling that we had addressed all the RTF issues and had formatted the safety data in a way that was optimized for FDA to understand it and query and audit it as efficiently as possible.

We left that meeting really eager to get the NDA to them. They asked us when we were going to file, which is always a good sign, and they seemed very eager to get the application.

With regard to an ODAC panel, I think it's very likely an ODAC panel will be scheduled. The last two or actually three melanoma drugs have had ODAC panels scheduled. One of those was ours when we filed our initial NDA, they did -- the Agency did schedule a May 12 ODAC, which obviously never happened. But the other two drugs that were approved last year also had ODAC panels scheduled but neither one ended up being conducted, so we think it's extremely likely an ODAC panel will be scheduled. It's anybody's guess whether it will really happen. From our perspective, we assume it will happen and we will have to prepare vigorously for it.

So really the crystal ball aspect of it really doesn't come into play. But I think it's very likely we will have one scheduled.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***
Fantastic. That's helpful. Thanks, Eamonn.

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

The last part of your question, we really believe we will get a six-month review, so we would be hoping for a PDUFA date right at the end of this year.

Operator

(Operator Instructions). Matt Dolan, Roth Capital Partners.

Matt Dolan - ***Roth Capital Markets*** - ***Analyst***
Good morning. Congrats on the progress. So I wanted to follow up on some of your commentary in Europe now that you've got a few procedures under your belt. Number one, once you get past this six to eight, can you give us some numbers over 12 to 24 months in terms of the number of centers that you could be in?

And then secondly on the utilization side or the revenue per procedure question, I know that you had your pick of the litter in terms of centers that had significant interest in adopting the system. Are there any volume commitments or that sort of thing that you could speak of that can maybe help us hone in better on how much volume will run through those centers? Thanks.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***President and CEO***
Well, as I mentioned, by the middle of this year, we expect to have six to eight centers up and running and in the second half of this year, we will be utilizing those centers to train other centers.

The contractual arrangements we have with these initial six to eight centers are that they have agreed to provide us with training for other centers in Europe in exchange for a number of things from us. The first thing that they get is a very comprehensive training program where we bring in a proctoring team, a clinical team that was associated with the clinical trials here in the United States to their facility and walk them through a number of procedures as well as a formal training program.

In addition, they get six free kits to do their six first six cases on us, so to speak, and they also get preferential pricing because they are our first customers and they deserve special treatment on the pricing side. I am happy to report that the pricing we have agreed to is significantly above what we are using for an average selling price in our model of $15,000. So appropriately, our models are conservative on the ASP side of things.

The first four patients that were treated at Milan will very likely have subsequent procedures, so Milan only got six free kits as the other sites did, so they have used four. They're going to need four more to do the next round on those same patients and they only have two left. So you can connect the dots there that we will -- we would anticipate an order from them going forward.

There are no minimum commitments from the sites. That was a bridge too far in these initial agreements and there are no limitations on how many sites we can run through their facilities to get training from them as they conduct cases.

Matt Dolan - ***Roth Capital Markets*** - ***Analyst***
Okay, maybe we'll follow-up off-line. Second question on some of your Phase II studies, walk us through the timeline there. I know you said second half. When could we see some data points that might imply platform expansion for CHEMOSAT out of those four trials you mentioned in your prepared remarks?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***President and CEO***
Sure, the four trials that we are anticipating starting in the second half of this year are two in colorectal, two in HCC. Of the two colorectal trials, one of them is a registration trial, which we anticipate will be conducted under a SPA or a Special Protocol Assessment, as was our melanoma trial in the United States, and we anticipate it will be approximately the same number of patients. About 100.

The other trial is a signal-seeking trial that is likely to be first/second line therapy plus standard of care versus standard of care. So a pretty exciting trial and we would -- that Phase II trial, our goal is to get patients enrolled before the end of the year.

The patients in the SPA registration trial, SPAs take a little longer to negotiate with the FDA and we think those patients, first enrolled patients would be probably more in the end of Q1, beginning of Q2 kind of timeframe.

On the HCC side, primary liver cancer, similar story. A registration trial that would start around the same time as the colorectal registration trial and would be approximately 100 patients under a SPA and a second line head-to-head Phase II against sorafenib, the standard of care for HCC.

That is a very exciting trial. It's I think a bold statement that we are very confident in our ability to show tremendous efficacy and Nexavar, sorafenib, the standard of care for liver cancer patients, has approximately a 3% response rate. And in our Phase II trial in HCC at the NCI, which has yet to be published but we've released topline data back in the fall, we had a very high response rate, although it was a small trial, we were very pleased with the data that came out of that.

So the net-net of all of that, it's going to be a very exciting clinical development program. Publications on the Phase II trials would likely take place in 2014 because those Phase II trials can enroll very quickly and show a response rate very quickly.

The SPA program, an enrollment will have late 2014 as -- early 2015 for publication timeframe. On the issue of publications, once we get our NDA application buttoned up, we would finally be in a position to get the publications under way because of the data being supplied, the FDA would have been finalized and carved in stone, if you will, with the NDA. So the authors would finally be in a position to get their Phase III and multiple Phase II studies published, and we would hope for electronic publication in late summer or early fall.

Matt Dolan - ***Roth Capital Markets*** - ***Analyst***
Great, thanks a lot.

Operator

A follow-up from Edward Nash, Cowen and Company.

Edward Nash - ***Cowen & Company*** - ***Analyst***
Thanks for taking my follow-up. I just wanted to see if we could just maybe jump ahead little bit. Your Generation 2 CHEMOSAT is the filter which is obviously one of the proprietary aspects and really kind of one of the things that you guys are really strong at in your technology is now up to 98% in filtering.

Are there any other tweaks or anything else that can be done to the system that could potentially create lower morbidity for the patient or easier physician use, anything out there that you guys could do to it, or have you kind of pretty much reached that already?

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***President and CEO***
No, Ed, we believe that there are lots of frontiers we can pursue to optimize the procedure and make it more patient-friendly and more clinician-friendly. Like with any new technology, it is very early in the game and although it works very, very well where it is with Gen 1, we are always going to be trying to improve it and without disclosing anything in the pipeline that is proprietary, I think it would be very reasonable to assume that there will be generation three, four, five, etc. as the product evolves over time. Those will likely be more incremental evolutionary changes more than revolutionary.

On the revolutionary side, we are very excited about the potential to do isolated lung and isolated brain perfusions and we have disclosed that that is on our horizon and are very, very excited about the prospects of making advances, clinical advances in those down the road on a timeline yet to be determined.

But as we evolve as a company, we are definitely looking to broaden the platform in a very rational way.

Edward Nash - ***Cowen & Company*** - ***Analyst***
Great, thank you.

Operator

Ladies and gentlemen, that does conclude the question-and-answer portion for today's events. I would now like to turn the presentation back over to Eamonn Hobbs for closing remarks.

Eamonn Hobbs - ***Delcath Systems, Inc.*** - ***President and CEO***
Thanks, Jeff. To recap, we are excited about 2012. European commercialization has begun for the first time outside of a clinical trial; CHEMOSAT is being utilized to benefit cancer patients; and physicians in the EU have important new modality for the treatment of cancers in the liver.

We continue to plan to complete and submit our NDA filing to the FDA by the end of the second quarter. We are also leveraging CE Mark approval in several international markets and are pursuing development and approval for CHEMOSAT with doxorubicin.

Finally, we are developing clinical programs aimed at expanding the CHEMOSAT product platform. We look forward to keeping you up-to-date on our progress. Thank you all.

Operator

Ladies and gentlemen, that concludes today's conference. You can access the replay by dialing toll-free at 1-888-286-8010, or international direct at 1-617-801-6888 and use replay code 90238135. Thank you for your participation. You may now disconnect. Have a wonderful day.