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): **May 11, 2012 (May 8, 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 May 8, 2012, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss the Company's financial results for the 2012 first fiscal quarter ended March 31, 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: May 11, 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

FINAL TRANSCRIPT
DCTH - Q1 2012 Delcath Systems, Inc. Earnings Conference Call

MAY 08, 2012 / 4:30PM ET

COMPANY PARTICIPANTS

Doug Sherk *Delcath Systems, Inc. - IR Contact -- EVC Group*
Eamonn Hobbs *Delcath Systems, Inc. - President, CEO*
Graham Miao *Delcath Systems, Inc. - EVP, CFO*
David McDonald *Delcath Systems, Inc. - EVP Business Development*

CONFERENCE CALL PARTICIPANTS

Edward Nash *Cowen & Company - Analyst*
Greg Wade *Wedbush Securities - Analyst*
Matt Dolan *Roth Capital Partners - Analyst*
David Musket *ProMed - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the first quarter 2012 Delcath Systems, Inc. earnings conference call. My name is Regina and I will be your conference operator for today. (Operator instructions).

I would now like to turn the conference over to your host for today, Mr. Doug Sherk. Please go ahead, sir.

Doug Sherk - ***Delcath Systems, Inc. - IR Contact -- EVC Group***

Thank you, operator, and good afternoon, everyone. Thank you for joining us today for this conference call and webcast to provide an update on Delcath's first 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. 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'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 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 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 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; Graham Miao, Executive Vice President and Chief Financial Officer; and David McDonald, Executive Vice President of Business Development.

Following their opening remarks, we will open the call to questions from analysts and institutional investors. To maximize the time allowed for Q&A, we ask you that you limit each question -- excuse me, we limit you to two questions and encourage you to re-queue to ask additional questions.

With that now, let me turn the call over to Eamonn.

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

Thanks, and good afternoon, everyone. Since our last update call in March, Delcath has made significant progress toward our goal of realizing the commercial potential of our chemosaturation system in Europe and around the world.

During our first quarter of 2012, the tangible results from the foundation we've laid over the past year began to emerge. Among the significant milestones achieved during the quarter and recent weeks are receipt of CE Mark approval for our second-generation hemofiltration cartridge for CHEMOSAT and the subsequent treatment of the first patient in Europe with our Gen Two system; presentation at the European Congress of Interventional Oncology of the first evidence of our generation two filter's ability to dramatically improve the side effect profile for chemosaturation therapy; addition of eight EU cancer centers to our initial launch and training program for CHEMOSAT, giving us a presence in five of our seven target markets; receipt of the first commercial orders for CHEMOSAT; final preparations for filing our new drug application with the FDA; regulatory approval in Australia for CHEMOSAT; and finally, we continued to strengthen the management team with the addition of pharmaceutical industry veterans Chris Houchins and Dr. Jennifer Simpson to our management team.

We believe that the approval of Gen Two, the initial clinical validation of its performance and its positive impact on post-procedure care presents some of the most important developments for chemosaturation therapy in recent years. It's where I'd like to begin the business of today's call.

On April 5th, we announced the receipt of CE Mark approval for the second generation hemofiltration cartridge of our CHEMOSAT system. As we've reported in the past, in bench and pre-clinical animal studies, Gen Two demonstrated melphalan removal of greater than 98% during drug infusion, and in the same studies showed removal of significantly fewer blood platelets than our previous generation filter. Based on these studies, we expected the benefits of Gen Two to be many and potentially game-changing.

We believe that dramatically improved filtration efficiency should significantly reduce or even eliminate material immune system and bone marrow suppression. Likewise we believe that the lower absorption of blood components should reduce the need for post-procedure blood replacement and an ICU stay for the patient.

Assuming these clinical benefits are confirmed, they could significantly lower post-procedure costs and improve the quality of the patient's life. In addition, these benefits may also help expand the potential patient population by adding the possibility of concomitant treatment with systemic therapies, and permitting treatment of patients too sick for treatment with the previous Gen One system.

With Gen Two, it may also be possible to shorten the interval between treatments, and may allow for more treatments in patients who are responding. We had very high hopes for Gen Two performance prior to the first patient being treated, and we are very excited to report that the system's performance in the first clinical procedure exceeded our expectations.

The first treatment with Gen Two was performed at the European Institute of Oncology, or IEO, on April 12th, and doctors there immediately noted the dramatic improvement in functionality and overall quality the new system represents. The case was performed on a patient previously treated with the Generation One system, and in the days following the treatment the IEO team reported the patient's post-procedure status and recovery time were all dramatically improved compared to the previous treatment.

Confirmation of these reports was provided at the recent European Congress of Interventional Oncology. Speaking at a symposium, Dr. Pierre Francesco Ferrucci, director of translational research on melanoma and medical oncologist at the IEO, presented a comparison of the side effect profiles following treatments with the Gen Two and Gen One versions of the system. The differences were very dramatic. Immediate post-operative care of the patient after the Gen Two procedure required no blood product infusions and no ICU stay, whereas the typical multiple blood product transfusions and ICU stay were required after the prior Gen One procedure.

In medical terms, the treatment with the Gen Two system showed brief grade zero to one, or mild bone marrow suppression, and no significant related toxicities. In the prior treatment of the same patient with Gen One, grade three, four, moderate to severe bone marrow suppression, and related toxicities were noted. Furthermore, the IEO team continued to report that the patient felt dramatically better following the Gen Two treatment, and that several aspects of post-procedure care had been reduced or eliminated entirely.

Dr. Ferrucci stated that if the side effect profile seen in the first Gen Two case is consistently repeated in subsequent treatments, then the Gen Two CHEMOSAT system has the potential to be a very significant step forward for this therapeutic approach to cancers in the liver.

Dr. Alessandro Testori, Director, Division of Melanoma and Skin Muscle Sarcoma and surgical oncologist at the IEO, was kind enough to share a letter he received from the first patient that received the Gen Two procedure. Since this patient had already received a Gen One procedure and had benefitted from an excellent response, she was in a very unique position to offer some insights into the benefits of Gen Two from a patient's perspective. I'd like to read a translation of the comments she shared with Dr. Testori following her Gen Two treatment.

Good evening Dr. Testori
Thank you for your interest.

From the very beginning, since we first met in your office, and you described the treatment that I would face, and I remember your smile when my only concern was my naiveté for any catheter. After discharge, I must say that my state of mind and body was fairly tried and worried, wondering if this new type of therapy would be effective for me.

Days later, I "enjoyed" the effects of physical therapy on my ending up in hospital to recover normal blood values. I will not hide the discomfort of this new unknown malaise unknown to come over me and continue day after day. My mood is what suffered most, and also my innate strong optimism was setback, so that when Dr. Ferrucci informed me of the need for a second perfusion I felt panic, so much so I was seriously considering not to repeat the treatment.

Believe me, I was really bad, then calmly, and knowing that I would be in good hands with you and your team, I decided to re-entrust myself to your care.

When I knew I'd be the first (in the world!) to address the perfusion with the new filter, this makes me a bit confused and worried but at the same time I told myself that perhaps this time, since the new device, it would be different.

And here we are today, and it is impossible to make comparisons between the two filters.

Leaving aside the obvious hardships related to hospitalization for the treatment, I can say that I feel really good, and I'm really happy. The physical and mental recovery was surprisingly fast. I hope that my state of mind is also effective in the outcome of care.
Thank you again for your interest, I find it really exquisite.

I offer my most cordial greetings
Grazia Melis

In summary, we are very excited, and now we're more convinced than ever that Gen Two represents a major game-changing improvement in the chemosaturation procedure. Through the tireless efforts of our R&D and clinical research teams we believe we have successfully transitioned CHEMOSAT from a therapy with an excellent efficacy with significant but known, manageable and acceptable toxicity, to a therapy with excellent efficacy and minimal toxicity, which in many ways addresses the long-sought-after idealized promise of targeted regional chemotherapy.

Upon receipt of the CE Mark for Gen Two, we converted our rollout in Europe and have re-scheduled training of new early launch centers to take advantage of the new Gen Two system. We believe we are attracting the interests of some of Europe's best cancer treatment and research centers. As I mentioned earlier, we recently secured agreements with eight additional centers to launch our CHEMOSAT system. The new agreements include our first sites in our target markets of Germany, France, Spain and the Netherlands, giving us a presence in five of our seven target markets. Training of the new sites is expected to begin in early June.

These centers 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. We believe that the network of training centers will ultimately provide a platform to develop a European base of expertise to help drive adoption of the CHEMOSAT system.

It's important to note that much of our initial commercial progress was achieved with the launch of Gen One, and that the intuitive nature of chemosaturation therapy and strength of initial data from our clinical trials helped establish an initial foundation in Europe. Physicians in Europe have treated patients with metastases from breast and gastric cancers as well as cutaneous and ocular melanoma.

We believe this indicates the potential that physicians see in chemosaturation therapy to help patients suffering from a wide variety of cancers in the liver. Early reports from the treating physicians are that all the patients have benefitted from the treatment and repeat treatments are being scheduled.

Successful use of the CHEMOSAT system at IEO ultimately led to the receipt of our first commercial orders for CHEMOSAT, a watershed moment for Delcath that marks our transition to a fully commercial enterprise.

Average direct-to-hospital sales prices for these orders have been well above the $15,000 used in our financial models, which produces gross margins typical of branded pharmaceutical products. All orders to date have been fulfilled with Gen Two product.

To further drive system adoption we continued to execute our strategy of detailing both oncologists and interventional radiologists about the benefits of chemosaturation therapy. As announced during the quarter, we have formally engaged Quintiles Commercials Ltd., a global leader in fully integrated market access services with extensive expertise in the oncology marketplace, to provide a dedicated team who will educate oncologists in the target markets about the potential benefits that CHEMOSAT could provide their patients.

Recruitment of this force is complete, training is in progress, and we expect the first field force members to start meeting with oncologists in June. This is important, since the oncologist typically has the greatest influence over how patients will be treated and will provide a push of patients toward the interventional radiologist who will actually perform the CHEMOSAT procedure. We're matching this “push” with a “pull” generated by our commercial support team, who will call directly on the interventional radiologists.

I'll turn now to the status of our NDA filing in the United States. I'm very pleased to report that we are in the final stages of preparing our NDA submission for the Gen One system. The very substantive work on clinical and safety data gathering from all of the clinical sites and migration to FDA-compliant clinical and safety databases is now complete.

This included the migration of clinical data for phase I, II and III studies from the database used at the NCI to a CDISC compliant database that allows us to provide data to the FDA in a more “FDA-review-friendly” manner.

We also created the Company's first safety database, which includes a pharmacovigilance and medical device database, and implemented a significantly expanded case report form that allowed capture of far more comprehensive and detailed data points related to the RTF, such as significant adverse events, hospitalization, concomitant medications, all labs and procedure-related data, all of which conservatively represents an addition of over 1.4 million new data points to the new database, which will be presented to the FDA in our NDA submission. Finally, we supported the hire of additional data entry staff at the clinical sites to aid with data entry and hired clinical research audit experts to prove our GCP, or good clinical practice, audit-readiness.

Although the collection of the data at each clinical site was very disruptive to their new clinical trial workflow, and took far longer than anyone desired, we wish to thank the research staff of each of the clinical sites for their flexibility, cooperation and dedication to this very important project to help bring CHEMOSAT to patients in the United States.

Now that the data has been fully collected and completely entered into the databases and monitoring of the safety data points has been completed, our last remaining task before we lock the databases is resolution of a relatively small number of outstanding database queries at each site. Queries are routine questions about individual patient data records and final reconciliation of the data. For example, a query could result from two dates not matching or similar but different terms used in separate records in a patient's history. We've informed all of the trial sites that the clinical database will be locked on the hard date of May 25th.

After we lock the database we will conduct final statistical analysis and complete the final NDA submission. We expect these final steps to take about 10 weeks from May 25th to complete, putting the submission of our NDA in mid-August.

Though this timeline has slipped slightly from our last call, I want to be very clear that we are very much in the final stages of this process and as a consequence we are completely confident in this final submission timeline.

The database lock date is also important with respect to publications. Once the database is locked on May 25th, the primary investigators will have all the information they need to finalize their manuscripts by dropping in the final data for our phase III trial and our multi-arm phase II trials, and then submit their manuscripts for publication.

Now that we have initial confirmation of Gen Two's outstanding clinical performance and major increased benefit to patient care, we believe it is in the best interests of patients to explore ways of accelerating availability of Gen Two to patients in the United States. We have submitted an amendment to our investigational new drug, or IND application, to include Gen Two in all future clinical trials, compassionate use cases and our expanded access program, and have initiated a dialogue with the FDA to discuss the optimal approval path for Gen Two in the US. From these discussions, at the very least we hope to gain insight to ensure that our NDA filing is optimized with regard to supporting a future Gen Two NDA supplement, which would be filed after the Gen One NDA is approved. At best, FDA might agree that we could file our NDA with Gen Two in August. Discussions with the FDA are continuing, and we will announce any developments as they occur in the coming months.

Let's turn now to our regulatory affairs efforts in international markets beyond Europe. We have already received regulatory approval in Australia and New Zealand, and we expect to begin supplying CHEMOSAT systems in these markets through an authorized third-party distributor in the second half of 2012.

We are actively engaged in discussions with distributors in several markets. As we previously discussed, we have also filed applications seeking regulatory approval in Hong Kong, South Korea, Singapore and Brazil, 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 Argentina, and the Middle East.

Turning to our clinical development program, we are continuing with our plans for the new clinical trials we have planned for the second half of this year. As reported last quarter, we intended to pursue four new clinical trials -- two in metastatic colorectal cancer and two in hepatocellular carcinoma, also called HCC, or primary liver cancer. We will include a United States registration trial in each of these two disease states.

As I mentioned a moment ago, we have filed an amendment to our IND application to permit the use of Gen Two in all these trials, as well as in our expanded access program. Assuming our Gen Two IND amendment is accepted, we expect to treat the first patient with Gen Two under our EAP in September of this year. But since CE Mark for Gen Two arrived a little later than anticipated we do not expect to enroll patients in the new clinical trials until the beginning of 2013.

We are also continuing to move forward with the development of a CHEMOSAT system with Doxorubicin, a chemotherapeutic agent shown to be effective in the treatment of HCC or primary liver cancer, and expect to receive CE Mark for our Doxorubicin CHEMOSAT system in the second half of this year. In conjunction with strategic partners, we intend to evaluate CHEMOSAT with Doxorubicin 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.

Now for a brief update on our business development activities, I'll turn the call over to Dave McDonald. Dave?

David McDonald - ***Delcath Systems, Inc. - EVP Business Development***

Thanks, Eamonn, and good afternoon, everyone. As many of you are aware, I transitioned full-time to my current role leading Delcath's business development and partnering initiatives at the beginning of the year. I'd like to take a few minutes now to update you on our recent activities.

The last three months have been a very active period on the BD front. Our efforts have been focused primarily in Asia, particularly China, as well as on clinical development partners in North America. Now while the timing of such partnerships is always difficult to predict, I'm very happy to report that we are meeting with considerable interest and having discussions with multiple parties currently.

We expect these potential partnerships to provide both financial and human capital to expand the CHEMOSAT platform into key Asian markets as well as support additional clinical studies that will drive commercial adoption worldwide and expand clinical indications in the US.

I'll also note that we're discussing potential collaborations for both melphalan and Doxorubicin, both in the US and internationally. As Eamonn mentioned, Doxorubicin is a drug of interest in China, given it's both approved and has a long history of use in the treatment of primary liver cancer.

Again, as many of you know, China accounts for just over 50% of the world's primary liver cancer patients and as such, it is the disease of interest in that country. The progress we've made in recent months on the Doxorubicin CHEMOSAT system is really what's driving this renewed interest of a potential partner in China.

So in summary, I'm excited about where we are regarding potential partnerships and look forward to updating you on future calls.

With that, I'll turn it back to Eamonn.

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

Thanks, Dave. I'll conclude my portion of our prepared remarks by recognizing the latest additions to our executive leadership team. Chris Houchins joined us in February as our Senior Vice President, Clinical and Medical Affairs, bringing with him over 21 years of experience in leading the global development and implementation of clinical, medical and scientific operations in oncology.

Chris's expertise will be invaluable as we execute our clinical development program I just mentioned. Chris joined us from Arno Therapeutics, where he was COO and SVP for clinical operations. Previously, Chris held senior leadership positions at Schering-Plough and Pfizer.

In April, Dr. Jennifer Simpson joined us as Executive Vice President, Global Marketing. Jennifer has an extensive background in pharmaceutical and oncology marketing and has been responsible for global product development in the oncology sector. Additionally, her experience as an oncology nurse practitioner, educator, medical science liaison and marketer, combined with intimate knowledge of the commercialization process, make her uniquely suited to help execute our plans.

Jennifer joined us from ImClone Systems, where she was vice president of marketing and oncology brand lead. Early in her career she held several leadership positions at Ortho Biotech, a Johnson & Johnson company.

We're pleased to welcome both Chris and Jennifer to the Delcath team.

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

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

Thank you, Eamonn, and a good afternoon, everyone. Let me begin by providing an update on the Company's financial condition. Our cash balance as of March 31, 2012, was approximately $20.8 million. 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 plans. Silicon Valley Bank is a well-recognized commercial lender in the life sciences field, and we are pleased to have established this relationship with them.

Turning to use of cash, our gross cash spend in the first quarter of 2012 was $14.7 million as compared to $7.8 million in the same period in the prior year. The increase was primarily driven by the NDA submission-related costs, staff increases in various functions to support commercialization in the EU, and the new EU headquarter operational cost in Galway. Average monthly gross spend was $4.9 million, which was in line with our expectation of between $4 million to $5 million a month. Taking into consideration the proceeds from our at-market equity facility, the net cash spend was approximately $10 million in the first quarter for a monthly average of $3.3 million.

Following submission of our NDA, which we expect to be in mid-August, we expect monthly cash expenses to decrease to around $3 million to $4 million for the remainder of 2012. We anticipate generating revenue in the second half of the year which will partially offset cash expenditures.

Turning to the income statement, for the quarter ending March 31, 2012, our operating loss was $14.6 million, which included approximately $0.9 million in non-cash stock-based compensation expense. G&A expenses were $7.4 million compared to $4.2 million for the prior year. The increase in G&A was primarily due to an expansion in staff, particularly for our EU headquarters in Galway, Ireland, and for sales and marketing support staff in the EU.

Research and development expenses were $7.1 million in the first quarter compared to $3.6 million in the prior year quarter. The increase was primarily driven by global regulatory efforts, including continued preparation of our NDA submission to the FDA, securing CE Mark with the Gen Two and expansion of addressable markets through the pursuit of additional regional regulatory approvals. With that, we are ready to take questions.

QUESTION AND ANSWER

Operator

(Operator instructions). And, Gentlemen, your first question today comes from the line of Edward Nash with Cowen & Company.

Edward Nash - *Cowen & Company - Analyst*

Hi. Good afternoon, everyone, thanks for taking my call. It sounds like you guys have had a very great and busy quarter.

Wanted to ask -- my two questions were first of all, could you give us some hard numbers on exactly how many patients have undergone the procedure under the old filtration system and how many have undergone the procedure now under the new filtration system?

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

Sure. The Gen One cases were seven, and we've had one Gen Two case so far. There are additional Gen Two cases planned for May at both the IEO and the University of Frankfurt, and of course all new centers will start with Gen Two as they come on board in June and thereafter.

Edward Nash - *Cowen & Company - Analyst*

Okay. And then my second question is just with regard to the first commercial sales that you said that you've now received, do we know exactly how many units that was for? Are you disclosing -- okay?

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

We haven't disclosed how many units. It's still in a relatively small number since both of the orders, we've had two orders. Both of them have come from the IEO, our first center that we got up and running.

Edward Nash - *Cowen & Company - Analyst*

Okay, perfect. I'll jump back in the queue. Thank you.

Operator

(Operator instructions). Gentlemen, your next question comes from the line of Greg Wade.

Greg Wade - *Wedbush Securities - Analyst*

Hi, good afternoon. Thanks for taking my questions as well.

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

Hi, Greg.

Greg Wade - *Wedbush Securities - Analyst*

Hi, good to hear your voice again, sir. I know you're not providing financial guidance, but could you tell us maybe in broad brushstrokes how many sites do you want to have online in Europe by the end of the year, and maybe what you would hope that number to be for the end of next year, if that's something you may share with us, please. Thanks.

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

The goal for this year is to have between 12 and 15 centers up and running by the end of the year. I think we're very comfortable that we'll have at least that many centers up and running.

The goal for the following year is much higher because those first 12 to 15 centers that we have doing cases this fiscal year or in calendar year are going to be the training centers for all the centers that we bring up next year.

So it's a bit of a domino effect that cascades forward as we get these training centers up and running. So 12 to 15 this year and then a much larger multiple of that next year.

Greg Wade - *Wedbush Securities - Analyst*

If I just might ask a follow-up question, it was I think very interesting to see that the first few cases done in Europe were outside of the ocular and cutaneous melanoma area. In your travels to meet with the centers, can you just maybe outline for us what people have been talking to you about, and the types of cases they plan to use, and whether you're seeing any barrier to the use of the product outside of where most of the data is in melanoma? And, thanks.

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

Well, absolutely. We have been getting tremendous interest outside of melanoma and neuroendocrine mets to the liver, which is where the majority of our data has been presented. Centers are very interested in HCC, in cholangiocarcinoma, in colorectal mets to the liver and of course we've already done our first breast cancer patient and gastric cancer patient.

So I think we're getting a great deal of comfort that the clinicians in the EU are seeing melphalan and CHEMOSAT as a hammer and cancer as a nail, and it really doesn't matter which type of primary got the cancer to the liver. At the kind of concentrations we're providing, there are no cancer cells that can stand up to that level of chemical bombardment.

Greg Wade - *Wedbush Securities - Analyst*

Thanks for taking my questions.

Operator

(Operator instructions). Your next question comes from the mind -- excuse me, the line of Matt Dolan with Roth Capital Partners.

Matt Dolan - *Roth Capital Partners - Analyst*

Hey, guys, good afternoon.

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

Hey, Matt, how are you?

Matt Dolan - *Roth Capital Partners - Analyst*

Good, thanks, Eamonn. So the first question is on Europe. As you transition to a revenue phase here in the second half of '12, what can you tell us about your level of confidence in gaining reimbursement at your centers at this point in the game, and therefore not see any disruption in the sales ramp as you shift from kind of, early trial phase to commercial phase, and maybe tell us when that switch is turned on to full aggressive commercial mode.

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

Well, the way reimbursement works for a new device is there are no specific reimbursements for devices. Devices are effectively reimbursed as a cost to a reimbursed procedure, and the hospitals we're working with are comfortable that they'll be able to get reimbursed for procedure codes that they already have.

So I can tell you that our confidence level is increasing from a couple of perspectives, because we are gaining traction, and two, the Gen Two clearly reduces the cost overhead of the procedure, which is to everyone's advantage in that the post-op care is greatly reduced with Gen Two because there isn't a requirement for an extended ICU stay and tremendous application of blood products and transfusions, and the medications to deal with the bone marrow suppression are dramatically reduced.

So the net-net is the overall procedure costs in handling a CHEMOSAT patient is reduced, which helps the hospital in their choice and methods of how to get reimbursed for whatever procedure they're tending to bill for.

Now, I would say that initially, as we roll out, the learning curve for the hospital in how to get paid is just as early and initial as our approach to them, so they find their way, but the administrators at the hospitals have been pretty comfortable that they're going to be able to get paid, since they do get paid today for other liver-directed therapies that are conducted by interventional radiologists, such as radioembolization and the like, which also has a similarly priced consumable and is conducted multiple times.

Matt Dolan - *Roth Capital Partners - Analyst*

Okay, so maybe just to clarify, do you expect that the transition to be smooth as we go into revenue phase, or should we kind of soften our ramp in Europe as you sort out some of those variables you just went through?

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

No, I think the transition will be smooth. Where a bump in the road appears with devices is typically not for 18 to 36 months post-commercialization, because the payers will eventually come back and potentially modify the payment or the reimbursement for CHEMOSAT by creating a new billing code for the CHEMOSAT procedure that's unique to CHEMOSAT.

And, if that reimbursement is less than what the hospital had been getting paid, that could create a bump in the road. But we're not going to face that for between 18 and 36 months, and that will vary dramatically country-to-country and sometimes even hospital-to-hospital.

Matt Dolan - *Roth Capital Partners - Analyst*

Okay, and then shifting to the US, just two points of clarification. One is what changed in your timeline from your call six weeks ago and then secondly, given -- sounds like your feedback and our feedback has been dramatic in terms of the side effects for Gen Two.

I know you said you can file a supplemental NDA. How should we think about just the general timeline for when Gen Two's on the market in the US, because that seems like that would be really the full US launch. Thanks.

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

Well, the first part of your question, what changed, all through the process of the data collection we have been a bit hat-in-hand going to the clinical sites and asking them for their attention to collect and input the data. We can't input it for them. The rules of good clinical practice are quite explicit in that the sites have to do their own data entry.

Now, when we received the RTF and agreed with a plan with the FDA to generate a very, very complete and comprehensive safety depiction of this new procedure, we went back to the sites that had already completed this trial in their mind, and all of the research staff, of course, wasn't waiting around, waiting for us to knock on their door. They were all very busy with new prospective trials, and we came back in and said, "Look, unfortunately we're not done yet. We have to go back to the patient records and we have to collect a tremendous amount of data." As I mentioned, conservatively, 1.4 million new data points.

So the sites have really dictated the timeline all along, because we can only go as fast as they would let us go, and we really didn't have the ability to tell them anything. We can only ask. We knew we were being disruptive, and we would agree with them on a timeline and they would make best efforts to hit that timeline, and needless to say, we didn't make most of those timelines over the last year.

So what changed over the last few months is once again the data was just not in the database, not completed in what was all of our expectations, which were really driven by the sites. So again, I don't want to point a finger at the sites and say anything other than thank you, because we're done, we've gotten everything, and we really appreciate all that they did for us to allow us to collect and amass this really comprehensive safety database that we're going to be putting into the NDA. But the fact remains the schedule has been dictated by their ability to input the data based on their time in between conducting prospective clinical trials on many, many other fronts.

I'm sorry, about the last --

Matt Dolan - *Roth Capital Partners - Analyst*

Yes, it was just about integrating Gen Two into your US launch, because it sounds like that'll be the real launch point for your domestic strategy.

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

Yes, Gen Two approval in the US is definitely a high priority. We are in conversation with the FDA about how to optimally get Gen Two approved, so there's no question. We want to get Gen Two approved and give patients in the United States access to Gen Two as quickly as possible.

The IND amendment that we submitted is a very complete and comprehensive package that compares Gen Two to Gen One on a technical and bench and pre-clinical basis that shows the comparability of the two filters from a technical perspective. So that submission will now allow us to have very

substantive conversations which we've already begun with the FDA about how to optimally get the NDA approved. So at this point in time we have no idea what the FDA is going to suggest is the right and optimal pathway for Gen Two.

In our prepared remarks what we tried to convey is there's a broad spectrum of possibilities here. The shortest path to Gen Two approval is if the FDA told us that they agreed we could add it into our NDA that we're filing in August. The other end of the spectrum is the FDA would say to us we will require additional clinical data for Gen Two approval, which would likely be a small, single-arm series to show safety. And, then the question would be would that be a post-approval or the clinical trial would have to be conducted pre-approval of an NDA supplement, or could we do a post-approval commitment?

So at this point in time it would be, I think, counterproductive to even venture a guess which way the FDA's going to go. Those conversations are going to take place and we'll -- I'm confident in the next few weeks we'll have a very clear picture of what the FDA is going to want us to do in order to get Gen Two on the market in the US in the shortest amount of time.

Matt Dolan - *Roth Capital Partners - Analyst*

Okay, thanks for all the time.

Operator

Your next question comes from the line of David Musket with ProMed. Mr. Musket, your line is open.

David Musket - *ProMed - Analyst*

Thank you. That was very helpful on the regulatory side. Are you still expecting an expedited review from the FDA on Gen One, if that's the way it goes?

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

Yes, we are expecting a six-month review. We of course won't know whether we have a six-month review until the NDA is accepted, which typically takes place about 60 days after filing.

David Musket - *ProMed - Analyst*

And, do you see a scenario, depending on how things go with the FDA on Gen Two, where you wouldn't actually launch Gen One?

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

Well, it's a very good question, and I can't see any scenarios where we would not launch Gen One unless we were extremely confident that Gen Two approval was imminent.

David Musket - *ProMed - Analyst*

Thank you, and can you just clarify -- I thought when you were going through the expense changes, what would be the change in the quarterly expenses post the filing, for the period for the end of the year going forward?

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

The changes that we forecast are [monthly] expenses to drop from between $4 million and $5 million to between $3 million and $4 million. And, why that is likely and evident is because the first half of this year and the last half of last year, our focus in the Company has been around the NDA resubmission.

The majority of our expenses associated -- or monthly expenses in total have been associated with the NDA resubmission, the clinical data gathering. Just the outside consultants dedicated to the NDA project would represent in excess of $1 million a month. So after we file the NDA, it would stand to reason that we will not require them in a similar capacity as they're working on right now.

David Musket - ***ProMed - Analyst***

Thanks for the clarification. I'm all set.

Operator

Ladies and gentlemen, this concludes the question-and-answer portion of our event today. I'd like to turn the call back over to management for some closing remarks.

Doug Sherk - ***Delcath Systems, Inc. - IR Contact -- EVC Group***

Thank you, operator. Before concluding our call today, we'd like to remind investors that Delcath will be holding its annual shareholder meeting on May 23rd in New York City, and we'll also hold an analyst day meeting on June 1st in Chicago immediately prior to the opening of the ASCO Congress. If you're interested in either of these events, please contact us, EVC, at 646-201-5445 for specific details. That concludes our call today. Thank you all for your participation.

Operator

Ladies and gentlemen, you may disconnect at this time. Have a great day.