UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): November 13, 2012 (November 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 November 7, 2012, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss the Company's financial results for the 2012 third fiscal quarter ended September 30, 2012 and recent operational progress. A copy of the transcript of the conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The information disclosed under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

Item 9.01. Financial Statements and Exhibits.

The following exhibit is filed herewith:

(d) Exhibits.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DELCATH SYSTEMS, INC.

Dated: November 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

THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

DCTH - Q3 2012 Delcath Systems, Inc. Earnings Conference Call

EVENT DATE/TIME: NOVEMBER 07, 2012 / 09:30PM GMT

CORPORATE PARTICIPANTS

Doug Sherk *EVC Group, Incorporated - IR*

Eamonn Hobbs *Delcath Systems, Incorporated - CEO, President*

Graham Miao *Delcath Systems, Incorporated - EVP, CFO*

CONFERENCE CALL PARTICIPANTS

Chris Lewis *Roth Capital Partners - Analyst*

Jason Mills *Canaccord Genuity - Analyst*

Greg Wade *Wedbush Securities - Analyst*

Jason Butler *JMP Securities - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Third Quarter 2012 Delcath Systems, Inc. Earnings Conference Call. My name is Erica and I'll be your coordinator for today. (Operator Instructions) I would now like to turn the presentation over to your host for today's call, Mr. Doug Sherk. Please proceed.

Doug Sherk. Thank you, Erica, and good afternoon, everyone. Thank you for joining us today for this conference call and webcast to provide an update on Delcath's third quarter 2012 results and recent corporate progress.

A replay of the conference call will be made approximately—will be available 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 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 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 allowed for Q&A, please ask two questions, and if you have additional questions, please re-queue to ask those additional questions. In advance, we thank you for your cooperation with this procedure.

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

Eamonn Hobbs - ***Delcath Systems, Incorporated - CEO, President***

Thanks, Doug, and good afternoon, everyone. Since our call with you in early August, the team at Delcath has achieved several significant milestones. Most important of these was FDA acceptance of our new drug application for our proprietary chemosaturation system with Melphalan Hydrochloride for injection for substantive review. As we announced recently, the FDA has designated a goal date of June 15, 2013. Acceptance of our NDA is the culmination of many months of work and we hope represents the first step towards U.S. commercialization.

Also during the quarter, we continued to implement our launch in Europe, completing applications for interim reimbursement in key markets and signing our exclusive distribution agreements in Italy and Spain. Recently, we also received regulatory approval for our Generation Two CHEMOSAT delivery system in Australia, and have satisfied all the requirements to affix the CE mark to the hepatic CHEMOSAT delivery system device for intrahepatic arterial delivery and extracorporeal filtration of Doxorubicin in October 2012, which helps establish a pathway for regulatory approval in large key Asian markets.

These developments help lay the foundation for realizing the full potential of our system in the U.S. and other markets around the world. After reviewing these achievements with you briefly, I will turn the call over to Graham for a review of our financial results.

I'll begin with the most important development for Delcath in many years, the FDA's acceptance of our NDA. This is a tremendously important development, not only for Delcath but for the patients in the U.S. who have a critical need for our treatment. We look forward to working closely with the agency throughout the review process with the goal of securing approval of our application. Our most important objective is to be able to provide patients in the U.S. with unresectable metastatic melanoma in the liver a new option for treating their disease.

The NDA was accepted with our generation two hemofiltration cartridge included as a technical change in the chemistry, manufacturing and control module of the NDA. Assuming our NDA is approved, this potentially represents the rapid availability of Gen Two for U.S. patients we've always hoped for, and will help enhance our launch of the system in the United States. Our NDA has been assigned a Prescription Drug User Fee Act or PDUFA goal date of June 15, 2013. FDA also advised us that we should expect an Oncology Drug Advisory Committee, or ODAC, panel to be convened as part of the review process. No date has been set and we will announce the date once it has been determined.

While we work with the FDA on review of our application, we continue to move forward with our expanded access program in the United States. As you know, the FDA accepted our amendments to our investigational new drug or IND application, and our EAP to include the Generation Two filter. These amendments permit physicians at select U.S. cancer centers to use the Generation Two system in expanded access and compassionate use cases after they obtain institutional review board, or IRB, approval. We expect to enroll six centers under the EAP, all of which were phase three trial sites, one of which has already obtained IRB approval, and the others are in various stages of their IRB approval process.

We are also working with each site to finalize the clinical trial agreements necessary to begin treatments under the program and we continue to expect patient treatments under the EAP program to begin this fall. This program will play a valuable role in providing access to patients in urgent need of our treatment while our NDA is under review.

As we said on our last call, the IND amendments also laid the groundwork for the use of the Generation Two system in the clinical trials we have planned as part of our clinical development program, and it is our intention to use Gen Two in all upcoming prospective clinical trials.

Turning now to Europe, we are continuing to execute on our rollout plan. As we stated previously, revenues for this year are expected to be minimal and weighted towards our fourth quarter with sales driven primarily by the centers we have activated so far and by third party distributors. Drivers continue to be the current status of reimbursement, which is critical to our commercialization efforts, and expanding our clinical experience. We continue to address both elements in parallel.

On the reimbursement front, a concentrated effort is underway in three EU markets we believe offer the quickest path to establishing reimbursement, namely Italy, German, and the U.K. In Italy, we learned this week that the CHEMOSAT procedure can be reimbursed under an existing diagnosis related group code, or DRG. This is highly significant news in that we believe it provides us with our first national reimbursement mechanism for CHEMOSAT procedures in Europe, and these procedures are now eligible to be reimbursed in Italy. We believe the reimbursement under this code will be between EUR11,000 and EUR16,000, depending on the region in Italy, and while not ideal we believe this provides a viable pathway to reimbursed procedures in Italy.

To potentially increase the level of reimbursement, we will continue to seek additional supplemental new technology payments and potentially pursue a new national DRG specific to CHEMOSAT.

In Germany, we have submitted two extraordinary insurance effort applications to date, and we and the sponsoring institution are awaiting response. These are case by case applications for reimbursement. Additionally, 12 centers agreed to sponsor a new diagnostic and therapeutic methods application, or NUB, as it's known in Germany. The German Radiology Society has also agreed to sponsor that application.

An NUB is a specific reimbursement payment for a new technology treatment paid to the sponsoring hospitals. If approved, this NUB application will be sufficient to provide referral coverage across Germany. We are hopeful that all of the reimbursement activity in Germany will lead to a positive response in the first quarter of next year and enable all German patients to be covered for CHEMOSAT procedures.

In the U.K., our lead centers are seeking to gain PCT, or primary care trust funding, which we hope will be granted in Q1 of 2013. This would allow us to perform CHEMOSAT procedures in three to four key centers in the U.K. with referrals being made nationwide. The U.K. is currently reorganizing its healthcare system and our partner centers are preparing to apply for reimbursement from a new national body in April. This will provide us with the opportunity to seek interim reimbursement for CHEMOSAT on a nationwide basis and it is worth pointing out that we are supported by key members of this new national body.

Pursuit of reimbursement in other key European markets is continuing, but the timeframe for success in these markets is a work in progress.

While we pursue reimbursement, we are seeking to build clinical experience by sponsoring investigator initiated trials, or IITs, with leading EU key opinion leaders that have approached us to support new clinical research. Currently, we hope to initiate one IIT of CHEMOSAT with Melphalan in primary liver cancer or HCC at a major institution in Germany in the first quarter of next year, and additional IITs are on the drawing board for centers in Spain, the Netherlands, and France for 2013.

In addition to building our clinical case, these small trials help drive clinical experience at key centers, which we hope will facilitate wider usage once reimbursement mechanisms are working and become available.

In addition to IITs, we also expect to activate our EU patient registry by the end of this year. This registry will serve as a standardized safety and efficacy database for up to 15 centers in all seven EU markets. Three of our initial launch and training centers are currently applying for ethical approvals and we expect that the first patient will be enrolled in the registry by the end of December.

Going forward, this registry will serve as a viable source of case studies and clinical outcomes and will further drive clinical adoption. As we have communicated in the past, our EU commercialization strategy includes a mix of both direct sale channels by our own field force, and indirect sales channels through third party distributors. During the third quarter, we entered into our first European third party distributor agreement with reputable companies in Italy and Spain, and we have already received the first distributor order for Italy. Of course, our ramp up in sales will continue to be dependent on the efforts to gain clinical adoption and regional reimbursement. The existing DRG code for Italy I mentioned earlier will be of particular benefit in the near term, while we pursue additional supplemental new technology payments and-or a new, higher reimbursing CHEMOSAT specific DRG in that country.

Turning to Symposia, at the Annual Meeting of the Cardiovascular and Interventional Radiology Society for Europe, or CIRSE, held in Lisbon, Portugal in mid-September, physicians from Italy and Germany shared their experience with, and benefits of, the Generation Two CHEMOSAT in treating patients with cancers in the liver. Specifically, they discussed CHEMOSAT's ability to directly treat the liver by addressing both visible tumors and micro metastases with higher dosing designed to improve tumor killing efficiency, thereby potentially allowing additional time to treat disease outside the liver that is not imminently life threatening. Later that month at the Annual Congress of the European Society for Medical Oncology, or ESMO, in Vienna, Austria, leading clinicians presented findings from their experiences in the use of CHEMOSAT and the potential role it may play in the management of European patients with cancers in the liver.

Both the symposia were well attended by clinicians throughout Europe and there is strong interest in offering patients the benefit of CHEMOSAT treatment.

Turning to other developments, we are pleased with the regulatory approvals we've received in the recent weeks. In late October, we received approval in Australia for our Generation Two CHEMOSAT delivery system device for intrahepatic arterial delivery with extracorporeal filtration with Melphalan. This approval is another significant milestone for Delcath since it represents our first approval of the Generation Two system in the Pacific Rim and enhances our opportunity to address a market of potentially $50 million to $70 million. We are currently evaluating multiple exclusive distributor candidates to help develop the Australian market.

To support clinical adoption and eventually training of CHEMOSAT with Melphalan throughout the Pacific Rim, we plan to initiate an IIT in primary liver cancer, or HCC, at Kobe University Hospital in Japan that we hope will eventually serve as our main training location for Asia.

As we announced recently, we have satisfied all of the requirements to affix the CE mark to the hepatic CHEMOSAT delivery system device for intrahepatic arterial delivery and extracorporeal filtration of Doxorubicin. This helps establish a pathway for regulatory approval in large, key Asian markets. Doxorubicin is an established chemotherapeutic agent commonly used in Asia to treat hepatocellular carcinoma, or HCC, which is the most common primary malignant tumor and is substantially more prevalent in Asia than western economies. Unlike Melphalan, the drug we used to launch CHEMOSAT in Europe and as part of our NDA in the U.S., Doxorubicin is approved and readily available in many Asian markets.

With the CE mark for delivery system device for intrahepatic arterial delivery and extracorporeal filtration of Doxorubicin in hand, we can now submit the product testing specifications to the Chinese State FDA for their evaluation by the end of 2012. In China, establishment of product testing standards would enable Delcath to import the CHEMOSAT system into China and use it in human patients for clinical trials. At the same time, we believe the CE mark for the hepatic CHEMOSAT delivery system device for intrahepatic arterial delivery and extracorporeal filtration of Doxorubicin should help us advance partnership discussions in China.

Meanwhile, the CE mark for the CHEMOSAT delivery system device for use with Doxorubicin, has put us in a position to submit a product registration for CHEMOSAT to the Korean FDA. We intend to submit this application by year-end. As with China, this submission activity should advance partnership discussions for the Korean market. With that, I'd like to turn the call over to Graham Miao for review of our financial results and then we'll take a few questions. Graham?

Graham Miao - ***Delcath Systems, Incorporated*** - ***EVP, CFO***

Thank you, Eamonn. Good afternoon, everyone. Let me begin by providing an update on the Company's financial condition. Our cash and cash equivalents as of September 30, 2012 was $28.3 million. We are pleased to report that we have been able to maintain a solid balance sheet in the third quarter. Our cash position as of September 30 is only $1 million less than where we stood as of June 30, 2012. The factors that lead to this development are as follows. First, our use of cash during the third quarter was $14.6 million, which was slightly higher than the second quarter. The use was primarily driven by NDA submission related costs, and ongoing EU commercialization efforts. Second, offsetting the cash spend in the third quarter were cash resources from the realizing of $4.4 million in September from 2007 warrant exercises. A modest amount from accounts receivable collections and approximately $9 million raised from our at-the-market, or ATM facility.

As of September 30, we had $21 million available through the ATM. We believe that our cash position and access to capital provide us adequate funds for our operating needs through our PDUFA date.

We continue our efforts to reduce operating costs and are committed to reducing average monthly cash spend in the fourth quarter to between $3 million and $4 million as a result of expected decrease in NDA related spend in the fourth quarter. In addition, we remain debt free, although we have a $20 million working capital credit facility with SVB. This facility provides us with additional financing options to access capital to support our commercialization plans, if needed.

Turning to the income statement, during the third quarter we recorded sales of $97,000 from the sale of CHEMOSAT kits in Europe, of which $39,000 was recognized in revenue and $58,000 was deferred revenue associated with initial order from a distributor in Europe.

As we communicated in the past, our EU commercialization strategy employs a mix of both direct sales channels by our own sales force and indirect sales channels through third party distributors. In the near term, we expect the revenue ramp to be slow and steady. But as Eamonn reviewed earlier, significant revenue growth is expected to occur once procedure reimbursement mechanisms are available and the clinical experience in Europe continues to grow.

For the third quarter ending September 30, 2012, our operating loss was $12.2 million, which included approximately $1 million in non-cash stock based compensation expense, as compared with an operating loss of $12.2 million, including approximately $0.9 million in non-cash stock based compensation expense, in the year ago period.

Selling, general, and administrative, or SG&A expenses, were $7 million for the third quarter of 2012, compared to $5.7 million for the same period in 2011, due to our ongoing commercialization efforts in Europe.

Research and development expenses were $5.3 million for the third quarter of 2012, compared to the $6.4 million for the same period in 2011. The lower R&D expenses reflect the anticipated lower consulting expenses associated with the preparation of the NDA submitted in mid-August 2012.

Finally, I would like to let our audience know that we will be presenting at the Lazard Healthcare Conference in New York on November 13 this year.

With that, we are ready to take questions.

QUESTION AND ANSWER

Operator

(Operator Instructions) And our first question comes from the line of Matt Dolan with Roth Capital Partners. Please proceed.

Chris Lewis - ***Roth Capital Partners*** - ***Analyst***

Hey, guys. This is [Chris Lewis] on the line for Matt. Good afternoon.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Hey, Chris.

Graham Miao - ***Delcath Systems, Incorporated*** - ***EVP, CFO***

Hey, Chris.

Chris Lewis - ***Roth Capital Partners*** - ***Analyst***

Just first off, could you provide some more commentary around the pace of procedures you're seeing in Europe and just maybe describe some of the general adoption patterns that you're seeing there with the training centers and the doctors there?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Well, the path we're following is we're focusing on really leading cancer centers in our target markets. And we currently have six centers that are actively doing cases. The program is we provide them with training and with some product to gain some clinical experience, and then we provide them with the support they need to recruit patients under either research funding or private pay funding while we work on reimbursement. So in Italy and in Germany we've had commercial orders [to date]. Two centers have actually gotten to the point where they had cases that they categorized as commercial and purchased product. Clearly, we're waiting for reimbursement to be established. And as I mentioned, just this week we learned from our reimbursement experts that an existing DRG was deemed to be appropriate by the Italian government reimbursement authority for use immediately as an interim reimbursement method. And although that doesn't pay as high as we ultimately would like to seek for reimbursement, it covers the majority of the cost of the procedure. And that we would expect is going to translate into removing a major barrier to commercial adoption, and allow for commercial adoption to accelerate in Italy.

Same as the—happening in Germany and the same thing is happening in the U.K. as far as very tangibly pursuing interim reimbursement. So once those click in, which we believe will be in the first quarter of next year or sooner, that will be very important.

Now, what we've seen from the cases that have been done is we've seen the product perform extremely well. We've seen Gen Two provide tremendous benefits in a number of ways. Patient tolerance for the procedures is much better. The days in the ICU are dramatically reduced, if not eliminated, and we've seen a wide variety of tumor types being treated. So not just melanoma, we've seen breast cancer, gastric cancer, primary liver cancer, gall bladder cancer, and I believe tomorrow there's a neuroendocrine case being done.

So it's slow and steady and we anticipate adding additional centers prior to the end of the year. And reimbursement is really the catalyst that we are working towards and we're making great progress on.

Chris Lewis - ***Roth Capital Partners*** - ***Analyst***

Okay, great. Thanks for the detail there. And then, just turning to the Asian market, how does the CE mark with Doxorubicin change the types of discussions you're having there with potential partners? And should we be expecting some type of partnership announcement here in the next six to 12 months or three to six months or maybe a better timetable there would be great. Thanks.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Well, certainly that's a very high priority for us and has been for a very long time. And to go back in history a little bit, we got very far down the road with a potential partner in China with our Melphalan system, and only to find out with our partner that although Melphalan was routinely used in China, it had actually never been approved as a drug for injection. So that put us in a bit of a tailspin in that we had to regroup. And our plan to regroup was to get our Doxorubicin delivery system

approved with a CE mark, and that is a very important milestone for us because now we can actually approach clinical use in China on the back of the CE mark for the device, as Doxorubicin is approved with very broad labeling in China and we believe our device can be approved in the Chinese system to deliver Doxorubicin in a rather straightforward way.

So we're just now back on track at being able to have substantive negotiations with regard to Chinese partnerships and we are working very hard on those. I would also add that although not directly related, the FDA accepting our NDA is—was very important to numerous potential Chinese partners. So now that the FDA has done that, we have that asset in our camp, if you will, and we're leveraging that as well. So although we can't put any timing on a potential Chinese strategic partnership, we're working very diligently on it and we are certainly seeing a significant amount of interest.

Chris Lewis - ***Roth Capital Partners*** - ***Analyst***

Okay, thank you.

Operator

Your next question comes from the line of Jason Mills with Canaccord Genuity. Please proceed.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Thank you. Hi, Eamonn. Hi, Graham. Thanks for taking the questions.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Hey, Jason.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

How are you?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Good, thanks. How are you doing?

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Very good. Thank you. Let's stick with Asia for a second. Do you have any sort of projections as to when you might see out of Asia revenue, any timing for initial commercial development there?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Well, definitely we wouldn't expect revenue in Asia until we have a partner in real terms. So the pathway to revenue in China, for instance, is find a partner and pursue state FDA approval of our device system for use with the already approved Doxorubicin. And that we expect would entail some clinical trials. Not very lengthy trials, but even a small trial is not without its timeline. So I think we're a ways away from material revenue in China. The first step is getting a partner signed up.

Now in Japan, we have some opportunities for short term revenue that center around working with leading key opinion leaders and their institutions to pursue clinical use of both Doxorubicin and Melphalan investigator initiated trials. So on the Doxorubicin side, we think we could get some revenue sometime in the next year, maybe 1.5 years. And the regulatory approval there for a Melphalan system would be—again, be dependent on local trials. So our partner there is going to be important as well. We did mention in this call that we have a relationship with Kobe University that we've developed over the last few years and are looking to expand that. So we do have a base of operations there in order to provide local data to potential partners.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Okay.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

On the Korean side, it's a Doxorubicin story very similar to China. And the other Pacific Rim, although not Asian—the other Pacific Rim market that is much more near term would be Australia and New Zealand, both of which have very per capita large markets in melanoma, our sweet spot.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Perfect.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

So we're at the stage where we're very actively involved in choosing our distributor for those markets and gaining the TGA, the local regulatory approval for our Gen Two system was a pivotal milestone there. So I would expect that we would have revenues in Australia and New Zealand sometime in 2013.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Okay. That's helpful color, Eamonn. Thanks. The next question, staying offshore in Europe, I think you mentioned you have six centers actively utilizing CHEMOSAT. How many centers are you negotiating contracts with now and sort of what do you expect by the end of the year the number of centers utilizing CHEMOSAT could be?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Well, I would expect another half dozen centers or so would be active before the end of the year. And we have many more than that signed up, but they're waiting for reimbursement to be established, so—which again, we think Italy we're now at a point where we have interim reimbursement established and we expect first quarter interim reimbursement in the U.K. and Germany.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Okay, that's helpful. Slip in one more and then I'll get back in queue. As part of the expanded access protocol, how many patients do you expect you'll enroll in that ultimately or maybe over the next 12 months? And will you book revenue as part of that or will that be part of the operating expense line?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Well, it's very hard to say how many patients will go through the EAP program. So it is really impossible for us to estimate. I think it's between—since it's between now and June, it—let's say we think it would be more than five and less than 30 as a wild guess. I don't think it will be 1,000 patients for sure. I think it will be a relatively small number. But at this point in time, we are not planning to charge for the systems, although we are revisiting that very actively at the moment. So—and the driving force in our desire to consider charging under the EAP program, which you're allowed to do up to the cost of the system, is not only to defer the cost of the system and our—its financial impact, but also to really initiate substantive conversations on a real basis with reimbursement channels in the United States.

Now, we can say that while we've been preparing the EAP, which is a formal clinical program, there have been compassionate use cases being conducted in the United States. We can't say how many. We can't say much about them at all other than they are a way for patients to access the therapy at certain centers. And we have been providing kits free of charge to those compassionate use cases. And we have been made aware by the hospitals conducting those compassionate use cases that they have been successful in obtaining reimbursement from private payers for those cases, which is a very good sign. And we'd like to—when we run the EAP program, we have a lot more insight into the ability and the negotiations on reimbursement than we do with compassionate use.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Right.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

So that's an attractive prospect.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Right. Just as a clarification for one of my previous questions, Eamonn, you said six are currently using it, but many more signed up. I think last quarter exiting the quarter you had 13. What's that number at right now?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Well, no, I was referring to—I thought we'd have an additional half dozen or six—.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

—Utilizing—.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

—By the end of the year. And currently we have six centers up and running.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Okay.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

I thought we'd have close to a dozen.

Jason Mills - ***Canaccord Genuity*** - ***Analyst***

Thank you.

Operator

Your next question comes from the line of Greg Wade with Wedbush. Please proceed.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Good afternoon, Eamonn.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Hey, Greg, how are you?

Greg Wade - ***Wedbush Securities*** - ***Analyst***

I'm good, sir. How are you doing?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Good, thank you.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Good. Hey, so let's just turn back to the expanded access program. Is it your plan to potentially begin charging on this program? And—.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

—Well, I just mentioned that actually. And we haven't made a decision yet. But I can tell you that we are very seriously considering that because of the ability for us to get into a substantive conversation on reimbursement far earlier than waiting until after FDA approval.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Okay.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

And our compassionate use cases are getting paid for, getting reimbursed. I shouldn't say our compassionate use. The compassionate use cases are being done under various institutions' protocols and IRBs, so we really don't have any insight into those other than we've been told by those institutions that they've been successful in gaining reimbursement.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Right, okay. And just remind us with respect to what you could potentially charge per device in this setting. It's up to a fully burdened cost—.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

—Correct—.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

—Per device, right, so pretty much whatever you want.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

That's right. Well, we would—considering all the investment we've made in this technology and how few we've actually made, practically speaking, we would be able to burden the cost quite significantly.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Okay, that's helpful. Thanks. So it would be sort of can I say a near commercial cost then?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Yes, I would think so.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Okay. And then, if I just might follow up. With respect to the reimbursement that's in place in Italy under this DRG, would the entire amount of that payment be available to—for the system or is that to cover all of the procedure related expenses for the patient? And I just have one follow-up.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

That is intended to cover all of the procedure related expenses. So we—as we mentioned during the call, the range depending on the region is between EUR11,000 and EUR16,000. And just like in the U.S. where reimbursements in New York City are far higher than those in Iowa, the same in Italy. So in the Milano area, Lombardy, we expect it to be on the higher end than the lower end. And that is a great step in the right direction in that at least that much of the cost is now paid for. Now, the situation in Italy is that we have a distributor that we sell to at a discount. So if we have to discount in the interim while we're pursuing higher reimbursement or a dedicated DRG, we can certainly do that and share that—share those discounts with the distributor. So the net effect to us is not as significant at all as it would be if we were direct.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Right. How much of that—how much of the percentage—the real percentage do you think is left over for the product versus the cost of doing—?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

—Well, the majority of the procedure cost to the hospital is going to be the CHEMOSAT system. The drug is extremely inexpensive and the procedure costs are relatively small. Many of the procedure workup costs are reimbursed under other codes currently, so they're not burdened on the procedure itself. And we've done extensive work in laying out the business case for CHEMOSAT in various European countries. So these reimbursements are pretty material. They're going to allow us to get moving right now. We're—we have applications in for interim new technology supplemental payments, which go on top of the DRG to the hospital to help defray some of the additional cost of new technologies like ours. And then ultimately, that can either become permanent or it can become—roll into a creation of a dedicated new higher reimbursing DRG for CHEMOSAT. So frankly, we're pretty pleased with the EUR11,000 to EUR16,000 reimbursement because that will allow us to get moving. That's a major step in the right direction.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

That's great, Eamonn. Thanks. I'll jump back in the queue.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Thanks, Greg.

Operator

(Operator Instructions) And the next question comes from the line of Jason Butler with JMP Securities. Please proceed.

Jason Butler - ***JMP Securities*** - ***Analyst***

Hi, thanks for taking the question. Eamonn, you kind of touched on it before, but maybe you could go into a little more detail about what you're actually doing in anticipation of FDA approval in terms of reimbursement in the U.S. What are the steps that you can take here to minimize the time following product availability that you can get paid for the product?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Sure, Jason. What we've been doing over the last couple of years actually is working through getting a dedicated CPT code, a category one CPT code, in the works and have lined up specialty societies to sponsor it. Now, the CAT-1 can't be applied for in earnest until we get FDA approval, so we're ready to go when we do get FDA approval. So that begs the question, what are we going to do in the interim? So what we'll do in the interim while we're waiting for the CAT-1 code is to work with each institution to go under unspecified 99 codes, which will allow them to get paid. But each of these are theoretically a one-off negotiation. So as I mentioned earlier, in the compassionate use cases we've been paying as much attention as we possibly can to how the institutions conducting compassionate use with CHEMOSAT have been successful in getting paid under 99 codes.

So the good news is they have been—these multiple institutions have been successful in getting paid and getting paid at a level where they—it wasn't prohibitive. Their administration allowed them to not only do it, but to do—continue to do it multiple times. And these are from very large, prominent private payers, so they're laying the groundwork. So as we move into post-FDA approval, we would have dossiers ready for new clinical sites to be able to present their arguments to the medical directors under a 99 code, while our CAT-1 code is in the queue, which normally takes approximately a year to 1.5 years.

Jason Butler - ***JMP Securities*** - ***Analyst***

Okay, great. Thank you very much, Eamonn.

Operator

Our next question is a follow-up question, which comes from the line of Greg Wade with Wedbush. Please proceed.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Thanks. Graham, didn't want to leave you. Can you just tell us how many options and warrants were outstanding at the end of the quarter?

Graham Miao - ***Delcath Systems, Incorporated*** - ***EVP, CFO***

I'm sorry?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

How many options and warrants were outstanding at the end of the quarter.

Graham Miao - ***Delcath Systems, Incorporated*** - ***EVP, CFO***

Yes. So we have at the end of the third quarter we have a total of 4.8 million shares of options and 5.6 million warrants. So if you want to calculate fully diluted numbers, then these two numbers (inaudible—accented).

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Okay. And then, Eamonn, when do you think the expanded access program could be put in place? Is there an approval timeline?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

The—it's pretty imminent. We have six centers in various stages of getting their internal approvals. We've been working with them for a long time. One center is—has gotten their IRB approval and they are lining up patients now. So we're hopeful that they'll be enrolling their first patients within the next month. The other five centers are very close to that same position. So our goal is that we are enrolling patients before the end—or before the end of the fall, which would be mid-December. So it looks pretty likely that's going to happen.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

And how will we find out whether you're giving away the product or selling it?

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Oh, we'll let you know. When we—when the EAP kicks off we'll likely announce that and that will be one of the things that we discuss, what the—whether we're giving the product away or charging for it.

Greg Wade - ***Wedbush Securities*** - ***Analyst***

Okay. Thanks for taking my second questions.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

My pleasure.

Operator

We have no further questions. I will now turn the call back over to Management for any closing remarks.

Eamonn Hobbs - ***Delcath Systems, Incorporated*** - ***CEO, President***

Well, I'd like to thank everyone for participating in today's call. We look forward to seeing you next week at the Lazard Conference, as well as updating you on our progress on the next quarterly call. Have a great day.

Operator

Thank you for your participation in today's conference. To access the replay for this call, you may dial 866-233-1854 or 617-614-4949 internationally, with the replay passcode of 87111973, again, 87111973. The replay will be available in approximately one hour's time. This concludes the presentation. You may now disconnect and everyone have a great day.