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 19, 2013 **(March 13, 2013)**

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)**	**(I.R.S. Employer Identification No.)**

810 Seventh Avenue, 35th Floor, New York, New York, 10019
(Address of principal executive offices) (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:

£ 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 13, 2013, Delcath Systems, Inc. (the "Company") hosted a conference call to discuss the Company's financial results for the 2012 fourth fiscal quarter and year ended December 31, 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

SIGNATURE

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.

Date: March 19, 2013

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 2012 Delcath Systems, Inc. Earnings Conference Call

EVENT DATE/TIME: MARCH 13, 2013 / 08:30PM GMT

CORPORATE PARTICIPANTS

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

Eamonn Hobbs *Delcath Systems Inc - President & CEO*

Graham Miao *Delcath Systems Inc - EVP & CFO*

CONFERENCE CALL PARTICIPANTS

Matt Dolan *ROTH Capital Partners - Analyst*

Jason Butler *JMP Securities - Analyst*

Greg Wade *Wedbush Securities - Analyst*

Marshall Berol *Encompass Fund - Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the fourth-quarter 2012 Delcath Systems earning conference call. My name is Derek, and I'll be your operator for today. At this time, all participants are in a listen-only mode. We shall facilitate a question-and-answer session at the end of the conference.

(Operator Instructions)

As a reminder, this conference is being recorded for replay purposes.

I would now like to turn the conference over to Mr. Doug Sherk. You may proceed.

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

Thank you, Derek, and good afternoon, everyone. Thank you for joining us today for the conference call and webcast to provide an update on Delcath's fourth-quarter and full-year 2012 results and recent progress. A replay of the conference call will be made approximately -- excuse me, a replay of the conference call will be made available and it will be made 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 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 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 the opening remarks, we'll open the call to questions from analysts and institutional investors. To maximize the time allowed for Q&A, please ask two questions, and if you have additional questions, please requeue to ask those additional questions. For webcast participants, questions can be submitted electronically by the webcast interface and questions will be summarized and addressed. Feel free to send us your questions during the course of this call and we'll summarize and address them during the Q&A session.

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

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Thanks, Doug, and good afternoon, everyone. After making some opening remarks, including a brief review of our achievements during 2012, as well as our priorities and potential key milestones in 2013, I'll turn the call over to Graham Miao, our Chief Financial Officer, who will review the financial results for the fourth quarter. Then I'll take your questions. We had numerous accomplishments during 2012. The most significant one was acceptance for review of our NDA for the Melblez Kit system by the US Food and Drug Administration. You will note that we have changed the brand name of our system here in the United States, a decision that resulted from numerous discussions our team has had with the FDA since the NDA was accepted for review back in October.

Melblez is our proposed brand name for melphalan. We continue to work closely with the FDA and its evaluation of our NDA, and we are quite focused on preparations for our presentation to the ODAC Panel on May 2. Our engagement with the FDA has been constructive, and we are very hopeful that the agency will conclude its review on the PDUFA goal date of June 15. Our team remains fully committed to bringing a new treatment option to US patients with unresectable ocular melanoma liver metastases.

Assuming we are granted FDA approval by the PDUFA date, our current plan is to begin US commercialization efforts in the fourth quarter of 2013. At this point, we would plan to market our product under the proposed trade name, Melblez Kit, which stands for Melblez melphalan for injection for use with the Delcath Hepatic Delivery System. We continue to develop our US launch plan for the Melblez Kit, with significant work being done in marketing, sales, and reimbursement. As part of our planning, we have begun a comprehensive pricing analysis in the US for the ultra-orphan disease state of unresectable metastatic ocular melanoma. There are currently no approved or effective treatment options for ocular melanoma metastatic to the liver, so there is a clear, unmet clinical need among patients suffering from this disease. Our objectives with the pricing analysis are to optimize the value for treatment with the Melblez Kit, establish economic basis for reimbursement, and ensure patient access to treatment.

Our initial marketing efforts in the United States would be focused on those hospitals that participated in our clinical trials and are part of our recently launched Expanded Access Program. These hospitals will provide a base of experienced procedure teams trained in the use of the Melblez Kit. Our focus will then expand to include other member hospitals of the National Comprehensive Cancer Network, which are centers of excellence for cancer care in the United States that see a majority of the advanced metastatic ocular melanoma patients. To address this market, we plan to build a small direct sales force, supported by medical science liaisons, which will provide clinical-based education to the healthcare professionals that make up the procedure team using the Melblez Kit.

With regard to our US Expanded Access Program, its focus is to provide eligible patients with access to treatment with our second-generation hemofiltration cartridge of the Melblez Kit while our NDA is under review by the FDA. Under the EAP, physicians at select US cancer centers can use the Melblez Kit in expanded access and compassionate use cases after they obtain Institutional Review Board, or IRB approval. The first patient under EAP was treated in January at Sky Ridge Medical Center in Colorado and had a second treatment in February. The Moffitt Cancer Center in Tampa has also begun enrolling patients. We expect to enroll up to six prestigious US medical centers that will offer patients access to the Delcath treatment option under the EAP Program.

Because the Melblez Kit should be used by physicians with a certain level of knowledge and training, we are planning to train medical oncologists, surgical oncologists, and interventional radiologists on proper procedure using the Melblez Kit. As with many new products in oncology, the FDA has indicated that, if approved, the Melblez Kit will have a Risk Evaluation and Mitigation Strategies, or REMS Program, which will provide required training to all treatment team participants in the procedure utilizing the Melblez Kit. The REMS Program will educate procedure team members on elements of safe use and training compliance. Our proposed REMS Program will be part of the ODAC Panel Review on May 2.

As with many product launches in the first year, reimbursement can pose a significant headwind following FDA approval. As a result, assuming our NDA is approved by the FDA, we plan to take steps to position us for a successful launch of the Melblez Kit from a reimbursement perspective. Following FDA approval, we intend to interface with payers, both private and Medicare, to discuss compelling reimbursement and access to the Melblez Kit and the associated procedures. Assuming our NDA has been approved, we currently anticipate submitting an application for a Current Procedural Terminology or CPT Category I Code in October of this year. With October 2013 submission, if the submission is approved, we anticipate the CPT would become effective in January 2015. In the interim, we anticipate that hospitals will use existing procedure-related codes to obtain reimbursement for Melblez Kit-related treatments.

One of our achievements in 2012 was the introduction of the CHEMOSAT Delivery System for melphalan in Europe. Following obtaining CE Mark for the Gen Two System, we entered into training and marketing agreements with 16 leading European cancer centers and today, nine of these centers have been trained and activated to provide CHEMOSAT treatments. To date, these activated centers have treated patients with a variety of cancers in the liver, a majority of which have been ocular and cutaneous liver metastases, but have also included hepatocellular carcinoma, or HCC, Cholangiocarcinoma, and liver metastases from breast cancer, gastric cancer, colorectal cancer, neuroendocrine tumors, and mucosal melanoma.

We are focused on seven target European markets -- Germany, United Kingdom, Italy, the Netherlands, France, Spain, and Ireland. We market the CHEMOSAT System for Melphalan in Germany, United Kingdom, Ireland, and the Netherlands through a direct sales force, have entered into distribution agreements in Italy and Spain and continue to seek a qualified distributor in France. We have also retained a contract field-based team of medical science liaisons to educate the medical oncology community in all seven target markets.

A critical driver of utilization growth for CHEMOSAT in Europe and, ultimately, revenue, will be the expansion of compelling reimbursement mechanisms for the procedure in each of the seven markets we are targeting. Mechanisms for partial reimbursement for the CHEMOSAT procedure have been established in Italy, and we are working with partner hospitals on supplemental reimbursement in specific regions. In Italy, the CHEMOSAT procedure can be partially reimbursed under an existing Diagnostic-related Group Code, or DRG, allowing hospitals to submit for partial reimbursement of the CHEMOSAT device and related procedure. We are also assisting hospitals from certain regions in applying for supplemental new technology payments to increase the level of reimbursement. In the Lombardy region, the application decision has been complicated by political uncertainty, which we hope will be resolved following the recently concluded elections. In addition, in conjunction with the European Institute of Oncology in Milan, we are evaluating the potential application for a new dedicated DRG code specific to the CHEMOSAT procedure.

In Germany, the Federal Reimbursement Agency granted Value 4 status to our application under the NUB Program, establishing a reimbursement pathway for CHEMOSAT procedures as a new technology treatment. While not mandating reimbursement, Value 4 status allows participating cancer centers to negotiate reimbursement for the CHEMOSAT procedure with all insurers serving their region. This Value 4 status has resulted in some of our participating cancer centers in Germany initiating negotiation with all payers that cover their region. While reimbursement is sought under the Value 4 status, we intend to work with partner hospitals to resubmit an application for Value 1 status after our Phase III trials are published, which we hope will occur later this year.

In the United Kingdom, leading cancer centers are seeking to gain Primary Care Trust, or PCT, interim funding, which we hope will be granted in the second quarter of 2013. PCT funding would allow CHEMOSAT procedures to be performed at those key centers that apply, with referrals being made nationwide. We are working closely with five of the key melanoma centers in the United Kingdom to achieve this interim funding. Due to current healthcare reforms in the United Kingdom, in April 2013, interim funding for oncological procedures will begin to move away from local PCTs to a centralized body, which may offer an opportunity to gain nationwide interim funding more quickly. The time frame for completing this change is currently unknown. We are also engaged with a Healthcare Resources Groups, or HRG, that decide on new HRG codes with a view to gaining a dedicated and permanent reimbursement code. At the same time, the National Institute For Clinical Excellence, or NICE, may decide to conduct a review of the CHEMOSAT procedure at any time, the outcome of which would determine our long-term reimbursement status. However, we do not anticipate an assessment from NICE until a significant number of CHEMOSAT procedures are conducted regularly in the United Kingdom.

Permanent compelling reimbursement in remaining EU markets will take some time to secure and, in the interim period, we are seeking payments through various avenues, including new technology programs. For example, in France, in order to obtain a permanent DRG code, the level of required data, both in terms of clinical trials and healthcare economics, is extremely high compared to other countries in the EU. We believe we will need the published Phase III trial manuscript, supported by investigator-initiated trial data, before submitting our application. We anticipate submitting our application in late 2013 and in the meantime, we are targeting the private market in France. Phase III publication is also a gating item for reimbursement in Ireland.

Development of compelling permanent reimbursement is a key driver of utilization and we are working closely with experts and our partner hospitals on various interim mechanisms. We have begun the applications project to secure compelling permanent reimbursement. Though these mechanisms have come online slower than we anticipated, which has impacted revenue ramp, physician interest in our therapy is strong. We remain optimistic about the long-term prospects for CHEMOSAT in Europe.

Now, I'd like to review our clinical development program. We are very excited about what we consider to be a robust clinical development program, the primary goal of which is to expand our US label indication beyond the initial indication we are seeking into much larger opportunities and also support clinical adoption and commercialization efforts in markets outside the United States. We believe execution of this program will ultimately drive long-term shareholder value. Over the longer term, we also intend to evaluate the technology platform for use with a variety of chemotherapeutic agents for the treatment of other liver cancers, as well as other organs and body regions. Our top priority is to pursue potential label expansion opportunities for our CHEMOSAT/ Melblez Kit System with melphalan in the treatment of other, more prevalent cancers in the liver. We are moving forward with plans for clinical trials in hepatocellular carcinoma, also known as HCC, or primary liver cancer, metastatic colorectal cancer, and neuroendocrine tumors with liver-dominant disease. We are in active discussions with the FDA on these proposed multi-center trials and subject to their agreement, we intend to begin enrolling patients for at least one of these new clinical trials in 2013.

In Europe, we plan to initiate a patient registry, which we will prospectively collect data from EU clinical experience. This registry will serve as a standardized safety and efficacy database, and as a means for clinicians to collaborate and share CHEMOSAT clinical experience and outcomes from up to 15 centers in all seven key EU markets.

We are also seeking to build clinical experience by sponsoring Investigator-Initiated Trials, or IITs, with leading EU opinion leaders that have approached us to support new clinical research. We believe these IITs will help grow clinical experience with CHEMOSAT at key centers and will support our effort to obtain compelling reimbursement for CHEMOSAT. In Taiwan, we are collaborating with our strategic partner, Chi-Fu Trading Company Limited, on a pivotal trial with melphalan for HCC, with the intent of obtaining regulatory approval from the Taiwan FDA.

Looking longer term, we believe that our proprietary drug/device platform may have broader applicability, including using other drugs to treat the liver, as well as for the treatment of cancers in other organs and regions of the body. As such, we currently have active development programs for the isolation and treatment of lung and brain cancers. We are also pursuing pharmaceutical partners to co-develop and fund clinical trials related to additional indications for our technology.

Turning to other anticipated key milestones in 2013, we have been working with the principal investigators of our Phase III melanoma and Phase II multi-histology clinical trials, and believe that submission of the clinical data to a peer-reviewed journal for publication could occur in the next several weeks. Additionally, publications characterizing the European clinical experience, using the CHEMOSAT System and the clinical benefit of treating liver metastases, have either been recently submitted or are in progress. In addition, we continue to work at leveraging the CE Mark for CHEMOSAT in order to expedite approval in other select countries as we have already done successfully in Australia and New Zealand. During 2012, we submitted applications for regulatory approvals for the CHEMOSAT System for melphalan in Hong Kong, Singapore, Argentina, and Brazil, and expect to receive approvals in most of these markets in 2013. We are pursuing strategic partners for development of CHEMOSAT in the People's Republic of China. As you know, in October, we obtained the right to affix the CE Mark to the CHEMOSAT Delivery System for doxorubicin. China represents a potentially large market for the Delcath CHEMOSAT Delivery System for doxorubicin with its primary liver cancer, or HCC incidence, accounting for an overwhelmingly large majority of the world's primary liver cancer patients.

With that, I'd like to turn the call over to Graham Miao for a review of our financial results and then we'll take a few questions. Graham?

Graham Miao - ***Delcath Systems Inc*** - ***EVP & CFO***

Thank you, Eamonn. Good afternoon, everyone. Let me begin by providing an update on the Company's financial condition. We raised approximately $21 million from our at-the-market, or ATM facility between January 1, 2013, and February 28, 2013, and that program has been successfully completed. As a result, our cash balance, as of February 28, 2013, was approximately $38 million. Because the ATM Equity program has worked well for us since its inception in December 2011, and, as a part of our efforts to strengthen our balance sheet, we have entered into an agreement with Cowen and Company to renew our ability to use the ATM equity financing strategy. We have a shelf registration designated for the ATM program, which we filed for review with the SEC this afternoon after the market close. Under the new agreement, Delcath may sell up to approximately $50 million in shares of the Company's common stock from time to time once the new shelf registration statement becomes effective. We believe this complements our existing, committed equity financing facility and strengthens our ability and flexibility to access capital.

As a reminder, the committed equity financing facility, or CEFF, was established last December and we used that month -- we used that facility that month to validate its utility. As of February 28 this year, the CEFF program has up to $32.8 million remaining with Terrapin Opportunity Fund. We believe that with our current cash balance and access to capital under the CEFF and ATM programs, we have the flexibility to execute our operating plans for the next 12 months and beyond.

Turning to use of cash, our cash utilization in the fourth quarter 2012, was $9.7 million, representing a 33% reduction compared to $14.6 million in the third quarter last year. This was consistent with the Company's previously announced expectations, with average monthly cash spent between $3 million and $4 million for the fourth quarter. The decrease in cash utilization was primarily driven by a reduction in consulting services following the submissions of the NDA, as well as overall effective cost management. We remain committed to maintaining our reduced cash utilization of between $9 million to $12 million per quarter for 2013.

Turning to the income statement, during the fourth quarter, we recorded revenue of $0.2 million. Operating loss was $11.8 million, which included approximately $0.9 million in non-cash stock-based compensation expense, as compared with an operating loss of $16 million, including $0.9 million in non-cash stock-based compensation expense in the same prior-year period.

Selling, general and administrative, SG&A expenses, were $6.4 million for the fourth quarter of 2012, compared to $6.1 million for the same period in 2011. The higher SG&A expense was primarily due to the increased EU commercialization expenses. Research and development, R&D expenses were $5.6 million for the fourth quarter 2012 compared to $9.8 million for the same period in 2011. The lower R&D expenses reflect lower consulting expenses following the submission of the NDA on August 15, 2012.

For the year ended December 31, 2012, we recorded revenue of $0.3 million and additional $30,000 of deferred revenue related to the orders from distribution partners. The Company's operating loss was a $53.9 million, which included approximately $3.8 million in non-cash stock-based compensation expense. The increase in expense is primarily related to EU commercialization efforts.

Operating loss for the year ended December 31, 2011, was $46.5 million, which included approximately -- excuse me -- $4.3 million in non-cash stock-based compensation expense. SG&A expenses were $28 million for the year ended December 31, 2012, compared to $21.3 million for the year ended December 31, 2011. R&D expenses were $26.2 million for the year ended December 31, 2012, compared to $25.2 million during the year ended December 31, 2011.

As Eamonn mentioned, we expect the revenue ramp to be slow in the near term until further progress is made on reimbursement front in Europe. We are continuing to work hard at establishing procedure reimbursement mechanisms in our target countries, which we believe, in combination with increased clinical experience in Europe, will help support future revenue growth. Finally, we will be presenting at the ROTH Conference on next Monday, March 18, at 3.00 PM Eastern Time. In addition, we will be conducting a Non-Deal Roadshow in Chicago next Thursday, March 21.

Now, I'll turn the call back to Eamonn.

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Thank you, Graham. To conclude, in 2012, we achieved a material reduction in our cash burn and had our NDA accepted for review by the FDA with a PDUFA date of June 15, 2013. We begin 2013 with a robust clinical development program in place and are making progress on obtaining reimbursement in Europe and have adequate cash and access to capital to execute our plans. Though challenges remain, there's much to be excited about and we look forward to updating you on our next quarterly call.

With that, operator, we're ready to take questions.

QUESTION AND ANSWER

Operator

(Operator Instructions)

Questions will be taken in the order received. Again, please limit yourself to two questions. Matt Dolan, ROTH Capital Partners.

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

I wanted to get a little more on your reimbursement strategy in the US now that you have narrowed the label you're pursuing. How does that play in to what you're expecting from a reimbursement perspective? And if you could, tie in what you anticipate upon launch in Q4 under the 99 codes And then what might come through the Category 1 and how we should think about pricing as a result?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Well, our plan for the United States is, as we mentioned, to utilize existing codes, including the 99 codes, until the new procedure codes, Category I CPT codes are approved and issued in 2015. So we'll have a little over a year prior to that to deal with existing codes.

With relevance to the change in the indication, narrowing to ocular melanoma, since there is no established treatment, and this is a completely unmet need for ocular melanoma patients with liver-dominant disease, we will be relying heavily on the unmet need pathway and our Phase III clinical trial data to support reimbursement efforts by hospitals who are conducting the procedure.

Because this is an ultra-orphan market, we would anticipate and we are currently working on a pricing strategy that would be reflective of an ultra-orphan marketplace. The therapy is a combination of the cost of our drug system, the Melblez Kit, and also the procedure reimbursement, which would be a DRG, ultimately. So, there is a little more complexity on the reimbursement side than if this was just a drug.

So to summarize, it's currently a work in progress on the pricing side. We anticipate that the pricing will be more reflective of an ultra-orphan market size than our current financial estimates in our investor presentations. And as soon as that's completed, we'll update those, which I would anticipate to be potentially by our next investor update.

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

Okay. I appreciate that. And maybe just to clarify one point. So the reimbursement that you'd obtain would be at a premium but include only the ocular melanoma patients, is that correct?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Well, if your question relates to the potential for reimbursement under 99 codes for off-label use --

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

Correct.

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Apologies. I didn't understand that originally. The procedure for gaining reimbursement is going to be based on clinical data, as it always is. So the question in my mind would be, would there be sufficient clinical data for a hospital to obtain off-label reimbursement based on our Phase II data, which was multi-histology in HCC, Cholangiocarcinoma, and NET.

So the answer to that question is going to be in the eye of the beholder, in the eye of the payer, as to whether that rises to the level of substantial or significant clinical data to support reimbursement. I'm afraid we're not going to know that until a hospital actually applies for it, whether or not they will be able to get reimbursement. And I'm not sure there's any way to gain any insight in that would be very robust at this time.

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

Okay. The second topic I wanted to touch on was the European ramp. You mentioned it will be fairly slow until reimbursement gets ironed out, but you gave us a procedure target last year. Is there anything you could give us from either centers or procedures or timing of clarity on reimbursement that might help us model out that side of the business? Thank you.

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Well, thanks, Matt. All we can say about reimbursement is the majority of our activities, at this point, are focused on gaining reimbursement. We've created a very solid beachhead in our seven target markets, with clinical centers performing procedures. Now all of our efforts, really, are focusing on pursuing -- helping them pursue reimbursement and where we are in that process, we went through in the presentation. It is clearly a work in progress and it varies country to country.

The publication of our clinical data, both our Phase III and our Phase II, factors into that. The Value 4 status was an achievement for us and under the NUB Program in Germany, which now allows the many hospitals that signed up for the program to pursue reimbursement. We have yet to have a hospital complete that process. We have multiple centers that have applied for reimbursement under that program and we're awaiting the outcome.

So the Italy partial reimbursement has been established, we are looking to bolster that. So unfortunately, from a modeling perspective, we're at the mercy of factors outside of our control as to if and when these reimbursement mechanisms come online. The good news is we believe they are coming online, albeit a bit slower than we had initially hoped. We will keep you apprised as they happen.

Operator

Jason Butler, JPM.

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

Eamonn, just wondering if you could give us any color on your current interactions with FDA? And maybe give us an overview of what you are preparing to -- or expect the FDA and the Advisory Committee to focus on during the panel? I know you talked about REMS but maybe you could talk about what, in terms of efficacy or safety, you might expect the focus to be?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Well, hi, Jason. Our -- definitely the tone of our FDA interactions has been very constructive. We're having very routine interactions with the agency, a lot of back and forth.

A tremendous amount of the interactions are related to the REMS Program and we anticipate ODAC is going to be very heavy on the REMS side. We have been told that FDA anticipates that there will be at least one, if not two, interventional radiologists on the ODAC Panel, which is obviously very unique. But very applicable from the perspective that is both a procedural and a medical oncology new technology.

So we would anticipate that there would be some procedural aspects of the Melblez Kit procedure. And the -- and also, the usual ODAC interactions with regards to the safety and a tremendous amount, since this is sole procedurally-oriented, of the anticipated agenda will be associated with REMS.

Now having said all that, the ODAC is a work in progress, we-- although we're in heavy preparation mode for ODAC, We won't submit a briefing package for ODAC until April 2, a month before the May 2 ODAC. We won't receive the questions until literally hours before the meeting, so -- or even the tone of the subject matter until a few hours. But those are our best guesses at this point, and we are looking forward to being very, very well-prepared for the May 2 ODAC.

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

Okay, great. Thanks. And then my apologies if I missed this earlier, but can you talk about what the use of the Expanded Access Program has been so far and what you expect it to be?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Well, the EAP Program kicked off in very late January at Sky Ridge in Denver, our first site. And an ocular melanoma patient was treated and then -- successfully -- and then was treated with a second round of therapy, which we believe is a very good sign in February. The Moffitt Cancer Center in Tampa, we anticipate will be the -- is enrolling patients and will be the second site to initiate procedures very, very shortly.

We anticipate that up to six centers will be involved in the EAP, but with all the variables associated with IRB approvals and patient scheduling, it's very hard to predict patient throughput for the EAP. Our anticipation longer term is that by PDUFA date, we would anticipate that we would have all, if not the majority, of the EAP sites up and doing procedures. There's certainly significant interest for them to do so.

Operator

Greg Wade from Wedbush.

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

A couple of quick questions. With respect to getting some Gen Two safety data in for the AdCom, how -- what's the procedure for that?

And then the following question is with respect to pricing. It seems you've got a choice, with respect to pricing here in the US, go with probably a very high price, which might price you out of off-label utilization or something lower in which off-label utilization may be more commonplace ahead of getting the label expanded. Can you just help us understand how you're grappling with this decision and what, maybe, market research you've done to help guide you in making it? Thanks.

Eamonn Hobbs - ***Delcath Systems Inc - President & CEO***

Sure. Well, Gen Two data into the AdCom is -- has always been something we've been very interested in providing. With the European experience and the current EAP Program underway, we are collecting data on Gen Two use that we plan to make available to the agency. The actual mechanics of how that data will be presented to the ODAC are pretty straightforward, in that they will be part of our briefing package and presentation and we certainly will be ready with slides to answer any questions that are presented at ODAC.

So a pretty standard AdCom situation is what I'd anticipate, any Gen Two issues being addressed with. With regard to pricing, it is a very good point. Clearly, our clinical development program broadcasts our belief and ambitions to broaden the label in the United States for our technology to far larger markets that we believe will be, hopefully, very well served by the technology as demonstrated by clinical trials.

So all that being said, after our hopeful approval for our initial indication, the on-label indication is going to be ocular melanoma, which is a relatively small patient population to be served. But a very, very significant unmet need in that patient population.

So where we are is our pricing strategy is a work in progress. We are working with outside experts to put together a cogent pricing strategy. And my -- although the strategy isn't completed yet, my crystal ball, if you will, would suggest that we will end up with more ultra-orphan pricing than mainstream, large-market pricing for a number of reasons. One, our initial indication is ultra-orphan and, two, it is extremely questionable whether pricing would have an effect, if any, on any potential decisions to use the product or not, considering the life-threatening aspect of the underlying disease. So I would hope that the pricing differential wouldn't factor into the clinical benefit equation as to whether or not it's appropriate for a patient that may not have the on-label indication. But, and that's clearly not our call.

Operator

(Operator Instructions)

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

We have a question from the webcast participants. Can you please provide an update on the Canadian approval process?

Eamonn Hobbs - ***Delcath Systems Inc - President & CEO***

Certainly. To update investors about where we stand with Canada. We had applied in Canada as a device, based on our CE Mark approval for our CHEMOSAT for the Delivery of Melphalan System approval, and had made tremendous progress with the Canadian Device Regulatory Authorities with regard to the potential approval and felt that we were getting very close to that approval based on interactions with them.

At the very tail end of that approval process, the drug side of the Canadian Healthcare Regulatory Authorities made a decision that, like the US, the system should be regulated as a combination product, requiring a new label for melphalan in Canada. With that in mind, we withdrew our device application and are now considering what our options are with regard to applying for a combination product approval in Canada, which most certainly would not take place prior to a US FDA approval. So at this point in time, any decisions to be made regarding Canada are tabled until we get past our PDUFA date.

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

Another question from the webcast participants is, with the cash balance at the end of February, about $38 million, can you explain the reasoning behind the timing for renewing the ATM now?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Certainly. The rationale for renewing the ATM right now is really associated with the -- ability to use the ATM in an opportunistic manner based on windows of opportunity that may or may not present themselves. So hypothetically, if the stock price went on a run to a very high value, which it has done in the past, that if we had an ATM in place, we would be able to avail ourselves of that opportunity and avail the investors with a financing that would be minimally dilutive compared to a financing or a more classic financing at a lower stock price.

So the real advantages of the ATM program center around the ability to access capital at the lowest dilutive manner that is available to us via various financing mechanisms. Also, the discounts and expenses associated with the ATM program are extremely competitive, if not, far more advantageous, than other financing mechanisms. So the combination of being opportunistic and speed to be able to access a hot market, if you will, plus the very low overhead costs and expenses associated with the ATM program, make it very attractive for us to have an ATM program at our disposal as part of a multi-pronged strategy to provide access to capital for the Company.

As Graham mentioned in his presentation, we also have an existing committed equity financing facility that provides us access to capital in a different way. But in some ways, provides us to access to windows of opportunity, maybe not as -- quite as -- quite the speed that the ATM program does. And then, of course, we have other mechanisms that we've used in the past, such as secondaries and the like.

So the reason to put an ATM program in place to initiate the start of an ATM program today is because our old program, we feel, was very successful, provided access to capital at a very low-cost. And that program has expired. So we would like to have a new one at our disposal that would be available for use at opportune moments in the future.

Operator

We have an audio question from the line of Marshall Berol, Encompass Fund.

Marshall Berol - ***Encompass Fund*** - ***Analyst***

Yes, thank you. On that, how long on the ATM program -- how long does that stay effective once it's approved by the SEC or reviewed by them?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Three years.

Marshall Berol - ***Encompass Fund*** - ***Analyst***

Okay. And the other question I have is these patients that are being treated, you said there's one and you expect another handful or so. On the EAP program, can that -- is that information used in connection with the advisory committee or the FDA meetings?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Yes. It certainly is -- all the information associated with the EAP program is readily available to the FDA since it's part of a clinical trial that is ongoing in the US. We definitely assume that, that data will be utilized by the agency and the advisory committee.

Marshall Berol - ***Encompass Fund*** - ***Analyst***

Do you anticipate that there will be any news releases concerning how the progress for those patients?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

No, that would be very, very unusual, if not outside the rules, to present any interim results associated with a clinical trial. But FDA would be avail -- would have very, very real-time understanding of how well those patients would be doing.

Marshall Berol - ***Encompass Fund*** - ***Analyst***

Okay, thanks. Well, good luck. Keep up the good work.

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

We have time for one more question from the webcast participants. That is, can you review the US market size for metastatic ocular melanoma?

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Sure. Well, the number of patients in the United States, we anticipate is, that have unresectable ocular melanoma that's liver-dominant, is approximately 1,600 and -- or approximately 1,700 patients out of a total -- that is approximately twice that. So, approximately 50% of patients with ocular melanoma develop liver-dominant unresectable disease and are -- we can -- what we would consider to be ideal candidates.

Now, with regard to the market size, there are two other factors that come in to play. The number of procedures that each of those patients would receive. And if we look to the Phase III, the average patient received approximately three procedures per treatment regimen. So that would appear to be a very reasonable estimate for market size.

Lastly, we'd apply the cost, or the average selling price of the system in the United States and the system is, of course, in the United States, the Melblez Kit, if approved, would be sold as a combination product, including both the drug and device. In our current investor presentations, we use $25,000 per procedure that would go to Delcath.

The -- as we mentioned earlier, we are currently studying and evaluating ultra-orphan pricing that we would anticipate would be significantly higher than $25,000 per procedure. But having said that, our current investor presentation utilizes the conservative $25,000 per procedure and that would equate to an on-label market size for ocular melanoma of $105 million for the US.

Operator

At this time --

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

There are no further questions from the webcast participants.

Eamonn Hobbs - ***Delcath Systems Inc*** - ***President & CEO***

Thank you. Thank you, everyone, for joining us today and we look forward to keeping you updated on our progress as we move forward. All the best.

Operator

Ladies and gentlemen, that concludes today's conference. We thank you for your participation. You may now disconnect.