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): December 10, 2012 (December 5, 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 December 5, 2012 Delcath Systems, Inc. (the "Company") hosted a webinar to discuss the Company's recent corporate developments. A copy of the transcript of the webinar 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. Webinar 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: December 10, 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. Webinar Transcript

THOMSON REUTERS STREETEVENTS
EDITED TRANSCRIPT
DCTH - Delcath Corporate Update Webinar

EVENT DATE/TIME: DECEMBER 05, 2012 / 10:00PM GMT

CORPORATE PARTICIPANTS

Gregory Gin *EVC Group - IR*

Eamonn Hobbs *Delcath Systems Inc - President & CEO*

Graham Miao *Delcath Systems Inc - EVP & CFO*

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and welcome to the Delcath corporate update. At this time, all participants are in a listen-only mode and will remain so for the duration of today's conference.

(Operator Instructions)

Please note that this conference is being recorded. I would now like to turn the call over to Mr. Gregory Gin of EVC Group. Please, go ahead.

Gregory Gin - ***EVC Group - IR***

Thank you, Operator; and good afternoon, everyone. Thank you for joining us for this webinar to provide an update on Delcath's recent corporate progress. An archived replay of the webinar will available approximately two hours after its conclusion, and it will be available for seven days on the Company's website at www.delcath.com.

Before we begin, I would like to remind you that some of the statements made during this webinar 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 in today's webinar are Eamonn Hobbs, President and Chief Executive Officer; and Graham Miao, Executive Vice President and Chief Financial Officer. Following their opening remarks, there will be in question-and-answer period. Questions can be submitted electronically via the webinar interface, and questions will be summarized and addressed. Feel free to forward us your questions during the course of this webinar and we will summarize and address them at the end.

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

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

Thank you, and good afternoon, everyone.

The purpose of today's webinar is to review the news we announced this afternoon after the market closed regarding our committed equity facility and modification of our new drug application, or NDA, pending with the US FDA, as well to provide a brief update on other recent corporate developments. I will start with the NDA and other developments, and then turn it over to Graham to discuss the committed equity financing vehicle.

Let's begin. We have had recent discussions with the FDA and are very appreciative of the FDA's interest in our NDA and the progress that has been made to date towards our June PDUFA goal date. Although the Company's Phase 3 trial demonstrated a very positive signal in patients with unresectable liver dominant cutaneous melanoma, based on the Agency's recommendation, we have decided to focus our NDA's indication for the treatment of patients with unresectable metastatic ocular melanoma in the liver. This is due to 90% of the patients enrolled in our Phase 3 trial having ocular melanoma metastases to the liver and the statistically significant efficacy data generated in the trial for this disease.

Additionally, FDA-approved treatment options have evolved significantly for metastatic cutaneous melanoma over the past several years, while treatment options for unresectable metastatic ocular melanoma continue to be lacking. This evolution, since our SPA was approved, has raised the regulatory bar for new drug approvals for treatment of cutaneous melanoma considerably. Given these facts, we believe that our data in metastatic ocular melanoma, coupled with the large unmet need for treatments in this disease, presents the most compelling case for our NDA, and the best opportunity for FDA approval of our chemosaturation system. We hope that a timely approval of our chemosaturation system will represent an important step to bring benefits to those cancer patients afflicted with this disease.

It is important to note that the modification of the indication in our NDA submission has not impacted our June PDUFA goal date. Remember that the FDA previously granted orphan-drug designation for melphalan in ocular melanoma, so assuming our NDA is approved, orphan-drug designation will provide Delcath with seven years of marketing exclusivity in this indication. Additionally, assuming our NDA is approved, we believe the decision to focus the initial labeling for our proprietary chemosaturation system on ocular melanoma will have little impact on our revenue potential in the United States. We believe that this is due to the fact that physicians in the United States typically prescribe any cancer treatment option based on clinical data and their professional medical experience.

While we are changing our request for labeled indication, the clinical data associated with our therapy remains the same and will continue to grow as we conduct further clinical trials. To that end, we plan to initiate clinical studies in 2013 to study the use of our chemosaturation system in other tumor types that potentially represent significant commercial opportunities beyond the ocular metastatic melanoma market. Currently, we intend to pursue studies to support label expansion for the use of our system to treat hepatocellular carcinoma and neuroendocrine cancer patients, and depending on feedback from the FDA, could potentially enroll our first patients before the end of 2013.

Before turning the call over to Graham, I'd now like to provide a brief update on the European launch of CHEMOSAT, where we are making steady progress. Physicians in Europe continue to treat patients with liver dominant metastases from a variety of tumor types, including both cutaneous and ocular melanoma, gastric cancer, breast cancer, and cholangiocarcinoma. We also have begun to see first patients with HCC, or primary liver cancer, and NET neuroendocrine tumors treated with CHEMOSAT in the European Union. We believe this illustrates how clinical data and professional medical experience drives usage of new therapies, as well as the broad potential that physicians see in using chemosaturation therapy to help patients suffering from wide varieties of cancers in the liver.

In early November, we reported the first national reimbursement mechanism for CHEMOSAT procedures in Europe under an existing Italian diagnostic-related group code, or DRG code. Establishing reimbursement across our targeted EU markets is critical to our commercialization efforts, and we are pursuing additional supplemental new technology payment programs in Italy, as well as conducting a concentrated effort to establish reimbursement in Germany and the UK, where we hope to receive positive reimbursement determinations in the first quarter of next year.

In Germany, a new cancer center at Gottingen University successfully performed its first CHEMOSAT procedure last week, bringing us to seven CHEMOSAT-trained launch centers in Europe so far this year. Gottingen University has also submitted a reimbursement application to a major private insurance carrier in Germany and received reimbursement. This is an interim mechanism we will attempt to leverage elsewhere in Germany until an expected decision by the NUB is rendered in the first quarter next year.

Also, we intend to build clinical experience with CHEMOSAT through investigator-initiated clinical trials by leading EU opinion leaders in tumor types where there is a large need. We believe these small trials will help build a growing body of evidence to support the clinical case for CHEMOSAT and help drive clinical adoption at key centers, which we hope will facilitate wider usage, once reimbursement mechanisms become available. In addition, these studies, if positive, will provide support of data for future US-registration trials in indications with a large need. Together with our reimbursement efforts, and with additional centers coming online in the next few weeks, we are building momentum for growth in Europe during 2013.

With that, I would like to have Graham Miao provide a review of the committed equity financing facility that we announced this afternoon, and then we will take questions. Graham?

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

Thank you, Eamonn. Good afternoon, everyone.

As part of our ongoing efforts to strengthen our balance sheet, we have established a committed equity financing facility, or CEFF, under which we may sell up to $35 million of our registered common stock to Terrapin Opportunity Fund over a 24-month period. This CEFF is a common financing resource that has been successfully used by late-stage development biotechnology companies. The new facility provides Delcath with the ability to potentially raise capital more efficiently by issuing shares at the time of our choosing. When, and if, we elect to use the facility, a modest discount would be applied to the purchase price, ranging between 3.6% and 5.8% to the volume weighted average price of Delcath's common stock over a preceding period of trading days. We are not obliged to utilize any of the $35 million facility, and we are free to enter into other equity and debt financing transactions, subject to certain restrictions. It is important to emphasize that no warrants are associated with this committed equity financing facility.

As you may know, in late December of last year, we established an At-The-Market, or ATM, financing program to sell up to $40 million in shares of our common stock from time to time. This new CEFF differs from the ATM by providing Delcath the ability to raise a larger amount of capital at one time as compared to the ATM. The CEFF also enables the Company to know where the shares are being held initially. In the Terrapin Fund, the investor has a successful track record with investments in the life sciences space. At the same time, the equity financing facility offers certain advantages over other financing strategies, including the ability to raise capital quickly, at a competitive cost, and it may allow us to manage dilution more effectively by issuing shares in multiple tranches at times of our choosing over the next 24 months.

This flexible financing facility is an important component of our portfolio of financing options. Combined with our $28 million in cash on hand at September 30, 2012, and an additional $21.5 million currently available under our At-The-Market program, we believe that the CEFF provides our Company with additional resources and flexibility required to execute our operation plan through our June 15, 2013 PDUFA goal date and well beyond. We continue to expect our average monthly cash expenses of $3 million to $4 million in the fourth quarter and anticipate maintaining this level in 2013.

That concludes our prepared remarks. We will be happy to take your questions online.

QUESTION AND ANSWER

Gregory Gin - ***EVC Group - IR***

Thank you, Graham.

As a reminder, questions can be submitted electronically via the webinar interface, and questions will be summarized and addressed.

(Caller Instructions)

The first question is — why did you choose to modify the label indication? Actually, this first questioner has two questions. The second question is — won't this narrower indication diminish the sales opportunity?

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

Thanks, Greg. I'll take a shot at that. Although our Phase 3 trial demonstrated a very positive signal in patients with unresectable liver dominant cutaneous melanoma, based on the FDA's recommendation, we have decided to focus our NDA's indication solely for the treatment of patients with unresectable metastatic ocular melanoma in the liver. As we mentioned earlier, this is due to the fact that our data is strongest in ocular melanoma, in that 90% of the patients in our Phase 3 trial were ocular melanoma patients, and the data is most compelling in that area.

Additionally, and very importantly, the world moved on during the course of the seven-plus years since the SPA was negotiated and approved by the FDA. When the SPA was agreed to with the FDA back in 2005, there were no treatments approved by the FDA for melanoma metastases of any kind, including cutaneous and ocular. So, the trial that was conducted by the Company agreed to under the SPA, really did not — was not designed to provide discrete data for each type, and the two types of melanoma were grouped together. I was not there at the time in 2005, but I would suggest that if I had been there I might have believed that there was no preassumption that there was any difference between how melanoma would react in the liver to a treatment, regardless of where it came from. And in fact, that still permeates the clinical mindset that melanoma is melanoma with regard to a cytotoxic agent in the liver. Since that time, multiple drugs have been approved by FDA to treat cutaneous melanoma, and the bar has risen significantly for what FDA is going to require to get a new — an additional cutaneous melanoma product approved and labeled for that.

Ocular, on the other hand, has not progressed. There are still no FDA-approved treatments for unresectable ocular melanoma, and none of the existing therapies has shown — has demonstrated benefit, to our knowledge. So, there is nothing existing, and apparently nothing in the pipeline for ocular melanoma, so the bar still pretty much where it was in 2005. Combining these two things — our data being extremely strong in ocular melanoma and the fact that the regulatory bar for approval in cutaneous melanoma has risen significantly, we were not surprised, I have to say, when FDA said — agreed, this is what we agreed to long ago, but the world has moved on, and we think — FDA told us in a recommendation, we think that you should focus your indication on ocular because there is still a very large unmet need there for these patients and you've shown significant benefit. That answers the question with regard to why we chose to limit the label.

The second part of the question about the diminished sales opportunity is really best answered by differentiating between label and clinical use. In oncology, clinicians choose therapies based on clinical data that supports the therapy, medical judgment, and very rarely does the label come into it. A label is extraordinarily important to provide access for clinicians to choose the medicines and therapies they are going to use, but the practice of medicine is not driven, by any extent, solely by labeling. We believe that the data has not changed. We are very comfortable in that. Regardless of what we do to our label, clinicians are going to use it in the way that they see fit as they were before. So, we do not believe this is going to reflect a change in our revenue opportunity going forward in the United States.

Last but not least, I'd point out that in Europe, we aren't seeing ocular melanoma drive the procedures. Certainly, ocular melanoma mets patients are being treated, but they are not dominating the patient mix. There are plenty of cutaneous patients being treated as well as HCC patients, neuroendocrine patients, gastric cancer patients, breast cancer patients, gallbladder cancer patients, cholangiocarcinomas, et cetera. So, we are seeing a very broad clinical adoption, and I think that speaks very loudly in how clinicians choose their therapies.

Gregory Gin - ***EVC Group*** - ***IR***

Thank you. The next question is — based on the CEFF financing, do you think you will have to sell more stock before you are profitable?

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

Let me address that. With this recent financing, we would have approximately over $80 million in available resources. Particularly based on the strong momentum we are seeing now in Europe and the prospect of entering the US market in 2013, we believe that the committed equity financing facility, along with ATM together with our cash on hand, provides us with the resources needed to execute our plan and cash expenses between $3 million to $4 million average per month through our June PDUFA goal date and well beyond.

Gregory Gin - ***EVC Group*** - ***IR***

Okay. The next question is — is Delcath charging for its EAP program, and how many cases — can you provide an update on number of cases?

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

The EAP program has yet to conduct a procedure on a patient. We are very close. One of the sites is actively looking to schedule a patient, so we are hopeful that they will this month. Other sites are in various stages of getting their local Institutional Review Board, their IRB, sign offs, and I think it is more likely that they will enroll patients and conduct procedures on them in, if we get lucky, late December, but with the holidays that may get in the way, and early January.

With regard to charging, we are still studying the opportunities to do that, and there is no question we would desire to do so, but we are using the EAP — we don't want to slow the EAP down, that's the best way to characterize it. And, since our PDUFA date is six months away, a little over six months away, a few weeks past that, it's pretty imminent, so we want to make sure the EAP gets going as quickly as possible, and if charging for the supplies slows that down, it becomes hugely problematic. That is where we are. We really don't have a hard-and-fast answer quite yet.

Gregory Gin - ***EVC Group*** - ***IR***

The next question is — can you provide an update on the potential regulatory approvals in ex-US, specifically Hong Kong and Canada?

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

In Hong Kong, we have regulatory approval for the Gen 1 and have Gen 2 regulatory approval pending, and we expect that any time. In Canada, we are in active — under active review and have routine interactions with the regulatory authorities there, so that is moving along very well — very hard to put a date on when their review will be completed. There is no statutory time limit, but we think they are in the near term, not the far term.

Gregory Gin - ***EVC Group*** - ***IR***

Next question is — can you provide an update on the entry into the Australian market?

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

We are very close to signing a distributor in Australia and New Zealand. We are fully approved there with Gen 2 and have been negotiating with a number of distributors and are down to the final negotiations now, so I would expect we will have a distributor signed up in Q1.

Gregory Gin - ***EVC Group*** - ***IR***

The next question is — in terms of using the ATM program going forward, do you anticipate suspending it given the CEFF financing program?

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

We believe both CEFF, certainly CEFF and ATM offers different features, and we believe they can coexist concurrently. Particularly now, we see certain advantages of a committed equity facility. So, once that is in place and depending on market conditions, we will utilize the CEFF because it does offer a larger amount at one time and the competitive price cost and also directly with an investor, but regardless, ATM will coexist until the program expires.

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

I would just add to that, echoing what Graham just mentioned, that both programs have their pluses and minuses, and we will use them to the advantage of the Company. Added together, along with our current cash on hand, we have ample funding to get us through PDUFA date, as Graham has mentioned. It is unlikely we will be using them at the exact same time.

Gregory Gin - ***EVC Group*** - ***IR***

The next question is — what is the population of patients in United States with unresectable metastatic ocular melanoma?

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

The population of patients that are idealized for our therapy, based on a number of estimates both internal and external, is approximately 1,700. With each of them requiring, on average, 2.5 procedures for a treatment course, and the patients in the Phase 3 received 3 treatments, that brings it out to 4,200 treatments for ocular melanoma. Once again, I would stress that that would be a fraction of how our product's being used in Europe, currently.

Gregory Gin - ***EVC Group*** - ***IR***

The next question has to do with the FDA review — are we still expecting FDA-panel review before June of 2013?

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

Are we expecting an FDA review?

Gregory Gin - ***EVC Group*** - ***IR***

Panel review —

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

Panel, excuse me — an ODAC panel review. Yes, FDA has advised us to expect an ODAC panel in May. So, the schedule for next year has yet to be set, and we asked them, because we are actively preparing, to narrow that down for us, and they said it was unlikely it was going to be in the February ODAC and the, potentially, the next one would be May. So, that is what we know so far.

Gregory Gin - ***EVC Group*** - ***IR***

The next question is — if approved by the FDA, what are your plans for reimbursement for the chemosaturation system in the United States?

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

We have an active program underway to create new codes, category-one codes, for our procedure. We are soliciting the support of various medical professional societies, which is all a normal part of pursuing new codes. In the interim, while those codes are being pursued, we would pursue unspecified codes, via negotiation with the insurance companies, so an interim reimbursement program not unlike what we are pursuing in Europe.

The good news with the United States compared to Europe, is Europe is an extremely fractionated continent that has independent, very independent-thinking reimbursement authorities across the continent, and each one has to be pursued in parallel, where in the US it is much more consolidated to the one system. The good news on US reimbursement is we have had compassionate-use patients that have been paid for by private insurance, and we take that as a very positive sign. That was negotiated between the treating centers and the private insurance that covered those patients that were receiving compassionate use.

Gregory Gin - ***EVC Group*** - ***IR***

The next question is — what do you estimate to be the revenue opportunity in the US annually for ocular metastatic melanoma?

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

We estimate the annual revenue opportunity, based on approximately 1,700 patients, to be approximately $105 million for ocular metastatic melanoma treatments.

Gregory Gin - ***EVC Group*** - ***IR***

The next question comes — how do you anticipate that the changes to the label that you are seeking for your NDA filing will impact the PDUFA date? And, this questioner has a second question — will this result in a delay?

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

We don’t anticipate any delay whatsoever. We are always hopeful of an earlier FDA decision that’s positive, but there is no impact on the indication change with regard to changing the PDUFA date to the negative. FDA, it sets a PDUFA date as a goal that they always try and beat, and I’m sure if they feel they have opportunities to complete their review earlier than the PDUFA date, they will do that. They have done that recently on a number of other oncology drugs, but we certainly have nothing other than crossed fingers and hope that that would happen. Right now, we are still assuming that we are on a timeline to the June 15, certainly no delays — no hint of delays has come up so far.

Gregory Gin - ***EVC Group*** - ***IR***

The next question is — based on interactions with the FDA, do you still expect the Gen 2 filter to be included in the potential June approval?

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

Yes, we do. We have had substantive and multiple substantive review interactions concerning Gen 2, and so far, so good. It is progressing through the review process as a technical change to the CMC module as an improvement in a Gen 1 filter, which it is. So, so far, so good.

Gregory Gin - ***EVC Group*** - ***IR***

We have received a number of questions to ask for an update on potential partnerships.

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

We are actively involved in a number of potential partnership negotiations. We really don't have anything to report today, other than we are very actively involved, and we have focused resources on bringing those deals to — those partnerships to fruition, but really don't have any further comment on those today.

Gregory Gin - ***EVC Group*** - ***IR***

The next question comes with respect to the clinical trial programs under consideration — is there an investigation of chemosaturation with lung cancer?

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

There is, we have a development program that is in the early stages to isolate the lung for primary lung cancer, and also to isolate the brain for primary brain cancer. We, to my knowledge, have not treated a liver-mets patient that had the primary be lung cancer. To my memory, I do not believe we have done that. But, if the question is referring to primary lung cancer in going after that, we are pursuing a development program to do that.

I would point out that it isn't that far down the road, with regard to concept anyway, because surgeons have done isolated lung perfusions with melphalan to validate the concept works. And of course, the surgical procedure is extremely complex and challenging for the patients, so a percutaneous way of doing that is being received very, very enthusiastically by the surgical community as potentially opening up a whole new way of treating primary lung cancer patients, so we are very excited about that.

Gregory Gin - ***EVC Group*** - ***IR***

With that, Eamonn, that is all the time that we have for questions. I will turn it over to you for any closing remarks.

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

Thanks, Greg. I'd like to thank everyone for participating in today's webinar. We are finishing the year with solid momentum in Europe, the real prospect of entering the US market during 2013, and in a strong financial position with approximately $80 million in available resources. Delcath has never been better positioned to generate returns for shareholders, and that is one of our key goals for the year ahead. We look forward to updating you on further progress. Thanks very much, everybody.

Operator

Thank you. Thank you, ladies and gentlemen. This concludes today's conference. Thank you for participating. You may all disconnect.

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