

**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 10, 2014 (November 5, 2014)**

DELCATH SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16133
(Commission File Number)

06-1245881
(IRS Employer
Identification Number)

1301 Avenue of the Americas, 43rd 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))
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Item 7.01. Regulation FD Disclosure.

On November 5, 2014, Delcath Systems, Inc. (the “Company”) hosted a conference call to discuss the Company’s financial results for the 2014 fiscal third quarter ended September 30, 2014 and recent operational development. 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 10, 2014

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

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EDITED TRANSCRIPT

DCTH - Q3 2014 Delcath Systems Inc Earnings Call

EVENT DATE/TIME: NOVEMBER 05, 2014 / 09:30PM GMT

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CORPORATE PARTICIPANTS

Michael Polyviou *Delcath Systems Inc - IR*

Jennifer Simpson *Delcath Systems Inc - Interim President, CEO*

Barbra Keck *Delcath Systems Inc - VP, Controller*

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PRESENTATION

Operator

Good day, ladies and gentlemen. And welcome to the Third Quarter 2014 Delcath Systems Earnings Conference Call. My name is Derrick, 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. Michael Polyviou of Investor Relations. Please proceed.

Michael Polyviou - Delcath Systems Inc - IR

Thank you, Derrick, and good afternoon, everyone. Thank you for joining us today for this conference call and webcast to provide an update on Delcath's fiscal third quarter 2014 results, as well as recent developments.

A replay of the conference call 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 also available at www.delcath.com, and the call will also be archived on the Company's 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 U.S. 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 events or circumstances after the date they are made.

Participating on today's call are Delcath's Interim President and CEO, Dr. Jennifer Simpson; and Barbra Keck, Delcath's Vice President and Controller. Following their opening remarks, we will open the call to questions from analysts and the institutional investors.

Additionally, in today's press release, we ask investors to submit questions via email that will be answered in the Q&A session. That email address is, mpolyviou@evcgroup.com, again, mpolyviou@evcgroup.com. Just a reminder, there is no assurance that all questions will be selected on today's call.

And with that, I will turn the call over to Jennifer. Jennifer?

Jennifer Simpson - Delcath Systems Inc - Interim President, CEO

Thanks, Michael, and good afternoon, everyone. On today's call I will provide an update on the recent activity in our clinical development program and our prudent pursuit of commercial development in the European marketplace. Later, I will turn the call over to Barbra Keck for review of our financials and then we will take some of your questions.

Let me begin with the expansion of our clinical development strategy for our Melphalan Hepatic Delivery System, which we refer to as Melphalan/HDS. In recent weeks, we revised and expanded this program to support the investigation of multiple tumor types in a cost efficient manner. The program's focus is on the generation of data in multiple tumor types in a controlled clinical trial setting and includes a global Phase 2 trial in primary liver cancer or HCC, and an additional cohort to study Intrahepatic Cholangiocarcinoma or ICC, as well as a global Phase 3 trial to study liver metastases from Ocular Melanoma. Additionally, the program will also include support from the Investigator Initiated Trials or IITs in cancers such as colorectal cancer that has metastasized to the liver. Cancers of the liver remain a major unmet medical need globally with approximately 1.2 million patients diagnosed annually with primary liver cancer or cancer that has metastasized to the liver. In the near term, we believe our expanded strategy will allow us to obtain proof-of-concept in the treatment of HCC and ICC, clinically validate the safety profile seen in commercial cases by treating physicians in Europe and position us to potentially pursue regulatory approvals in at least one of these tumor types.

I will spend a few minutes highlighting these efforts, as there has been significant progress in all three indications since we last spoke in August.

Beginning with our global Phase 2 trial in HCC, two centers, Johan Wolfgang Goethe University Hospital, known as JWG in Frankfurt, Germany and Moffitt Cancer Center in Tampa, Florida are now enrolling patients. We anticipate opening an additional four to seven centers in Europe and the U.S. Subject to timely enrollment, we anticipate having interim data on the first 11 HCC patients in this trial available by mid 2015.



Recently, we've taken steps to expand the European Phase 2 trial at HCC to include a cohort of patients with Intrahepatic Cholangiocarcinoma, or ICC. ICC is a tumor in the bile duct that arises within the liver and is the second most common primary liver tumor, and which accounts for 3% of all gastrointestinal cancers. Outside of resection, which is the only cure for ICC, there is no standard of care. The trial for this cohort will be conducted at the same centers participating in the HCC trial in Europe and is expected to be open for enrollment by the end of this year.

As a reminder, based on differences in treatment practice patterns and regulatory requirements between Europe and the U.S., we have established separate European and U.S. Phase 2 clinical trials with different inclusion and exclusion patient selection criteria. Clinical observations from the trials are designed to be complementary, and are expected to be analyzed collectively. If positive results are achieved, this will help support a future Phase 3 pivotal study design that would evaluate overall survival. The trials will also incorporate additional safety measures from experience gained from EU commercial cases as well as the U.S. Ocular Melanoma program.

In Europe, the Phase 2 program will investigate the safety and efficacy of Melphalan/HDS treatment without sorafenib in patients with unresectable liver cancer confined to the liver. In the U.S. the Phase 2 program will investigate the safety and efficacy of Mephalan/HDS treatment followed by sorafenib in patients with unresectable liver cancer also confined to the liver. The primary objective will be to evaluate tumor response, or objective response rate, as measured by Modified Response Evaluation Criteria in Solid Tumor, also known as modified RECIST. Secondary objectives will assess progression-free survival, safety, and if sorafenib is utilized, the safety of sorafenib following treatment with Melphalan/HDS. Additional analyses will be conducted to characterize the systemic exposure of Melphalan administered by Melphalan/HDS, as well as an assessment of patient-reported clinical outcomes or quality-of-life measures. The interim data we expect from the first 11 HCC patients will provide a proof-of-concept signal in this tumor type to support continuation of the trial and eventually a Phase 3 registration trial if results are positive. Additionally, a positive efficacy signal from the ICC cohort may provide a potential path to a registration trial. Combined safety data from the HCC and ICC cohort will also provide valuable safety analysis to provide to the FDA.

We are also planning to sponsor a clinical trial in Ocular Melanoma with liver metastases. We believe this Phase 3 trial could give us the fastest path to a New Drug Application, or NDA, regulatory approval in Ocular Melanoma with liver metastases. According to the American Cancer Society and other international health agencies, approximately 8,600 cases of Ocular Melanoma are diagnosed annually in the United States and Europe, with more than half of these patients expected to develop liver metastases. Again, there is no standard of care for patients with Ocular Melanoma with liver metastases.

We are advancing plans to initiate a pivotal global Phase 3 overall survival clinical trial and we will be working with the FDA and the relevant health authorities in Europe prior to initiation with a view to opening the trial in mid-2015. We anticipate submitting a meeting request to the FDA by year end and expect a meeting sometime in Q1 2015.

Based on the strength of the efficacy data obtained in our original Phase 1, 2 and 3 programs and the reports of an improved safety profile from over 130 patient treatments performed in a non-clinical trial studying in Europe, we are confident this Phase 3 trial program can address the concerns raised by the FDA in its Complete Response Letter.

In addition to these trials, we are supporting two investigator-initiated trials in Europe. The first is in colorectal cancer that has metastasized to the liver at Leiden University Medical Center in the Netherlands, which is open and has enrolled six patients to date. Early data presented by the lead investigator shows responses in these patients. If the overall study is positive, this may provide another treatment option for patients in Europe with metastatic colorectal cancer.

The second study, in HCC at JWG in Germany is open for enrollment. We believe IITs will serve to build clinical experience at key cancer centers, identify additional efficacy signals and will help support efforts to obtain reimbursement in Europe. Our team continues to evaluate additional investigator initiated trial proposals as they are submitted.

Lastly, on the clinical development front, our European patient registry will be activated in Germany by year end. The registry will prospectively collect data from EU commercial experience that the Company believes will provide valuable support of its efforts for clinical adoption and commercialization in Europe.

In illustration of the continued interest leading clinicians have in the potential of this therapy occurred just last week at the European Society of Surgical Oncology Congress, or ESSO. Three abstracts summarizing the clinical experience of three hospitals in Europe and the U.S. were accepted by ESSO for presentations. The centers were Moffitt Cancer Center, University Southampton in the U.K. and Leiden University Medical Center in the Netherlands. The data, as updated by the authors during oral presentation, reported on a total of 44 patients that received 91 treatments across all three institutions in a combination of commercial as well as clinical trial cases among multiple tumor types. Moffitt Cancer Center reported on 13 patients. Nine patients had Ocular Melanoma and 67% of those patients had a partial response. In addition, one patient was reported to have a complete response. The remaining patients either had stable disease or disease progression. Other tumor types that were treated were cutaneous Melanoma, melanoma of unknown primary and leiomyosarcoma. Of note, Moffitt Cancer Center reported that several patients had received four treatments, and two others received five and six treatments, respectively.



Leiden University Medical Center reported on 11 patients of which five patients had Ocular Melanoma and six patients had metastatic colorectal cancer. Of the Ocular Melanoma patients, 80% had a partial response. Of the metastatic colorectal cancer patients, four patients have had scans to date and demonstrated a 50% partial response. For the remaining two patients, it was too early to perform scans and assess tumor response. Remaining patients either have stable disease or disease progression.

Lastly, The University Southampton reported on 20 patients with Ocular Melanoma of which 19 received treatment. Of those patients treated, 47% had a partial response and 16% had a complete response. Remaining patients either had stable disease or disease progression.

These response rates were achieved with the range of one to six treatments. All authors concluded that CHEMOSAT or Melphalan/HDS is a safe and effective procedure for selected patients. These abstracts, as submitted, can be downloaded from the ECCO-ESSO website. A link to this site is available on delcath.com.

Now turning to our commercial efforts in the European market. Clinical adoption of CHEMOSAT treatments continues to be steady, which we believe is a function of expanding clinical experience and approval of individual funding requests. Through the end of October 2014, 62 CHEMOSAT procedures have been performed in Europe, including 27 retreatments. This compares to 30 treatments, including nine retreatments, performed during the same period in 2013. Clearly there has been a significant increase in the clinical adoption of CHEMOSAT in Europe. Since CHEMOSAT became commercially available in early 2012 and through October 31, 2014, 133 treatments have been performed on 90 patients at leading clinical centers in Europe. We are encouraged with this progress and we would anticipate increased interest as clinicians become more aware of the benefits and reimbursement opportunities expand.

Now turning our attention to our continuing efforts for reimbursement. In Germany, individual funding requests or IFRs continue to be the primary means of reimbursement for CHEMOSAT procedures until permanent reimbursement is in place. These applications are submitted for individual patients and reviewed on a case-by-case basis by insurance providers. We continue to see a majority of these applications being approved and are hopeful that this trend will continue.

As we have previously discussed, in January, we were granted NUB Value 4 status for 2014 interim reimbursement in Germany, which provides hospitals the opportunity to negotiate a budget to fund CHEMOSAT procedures with the regional insurance carriers. While we are pleased that hospitals in Germany have the option of negotiating reimbursement under this mechanism, unfortunately we have observed that hospitals primarily focus their resources on NUB Value 1 interim procedures and accordingly we believe the IFRs will be the primary source of coverage in Germany this year for CHEMOSAT. Hospitals submitted the 2015 NUB application last month. The 2015 application received the support of the DHGO, which is the German Society of Oncology and Hematology in addition to the support of the German Radiology Association, which had supported previous applications. The decision on NUB status for 2015 is expected on or before February 1, 2015.

In the U.K. centers have applied for a block-funding grant for a limited number of patients with melanoma via the Commissioning Through Evaluation or CTE. The mechanism under which block funding is granted is new, and ongoing delays in policy changes in the National Health Service, or NHS, make it difficult to predict the likelihood and timing of block grant funding. However, we are currently awaiting a decision and if it's made this quarter, potential funding would then be available in the 2015 first quarter. The current application seeks funding for 50 to 75 Ocular Melanoma patients and 15 to 20 cutaneous melanoma patients.

With that, I'll now turn the call over to Barbra Keck for review of our financial results.

Barbra Keck - Delcath Systems Inc - VP, Controller

Thank you, Jennifer.

During the quarter, net cash used in operating activities was \$4.0 million, at the low end of our \$4.0 million to \$5.0 million quarterly cash utilization projection, the sixth consecutive quarter of meeting our projections.

For the first nine months, net cash used in operating activities was \$12.4 million, a 57% reduction compared to \$28.9 million in the comparable period in 2013. The reduction was driven by the decrease in NDA submission-related cost, the phasing out of the Company's medical science liaison program and improved organizational and operational efficiencies. Importantly, we have met our cash utilization guidance for the last six quarters. We expect our average quarterly cash utilization to be between \$4.0 million to \$5.0 million for the fourth quarter. As of September 30, 2014, cash and cash equivalents were \$23.3 million. We believe that the actions we have taken and resources we have available today are adequate to fund our operations through the next 12 months.

Turning to the income statement, for the third quarter ended September 30, 2014, we recognized total product revenue of \$217,000, compared with total product revenue of \$72,000 in the year-ago third quarter. For the nine months of 2014, total product revenue was \$778,000, compared to total product revenue of \$152,000 for the same period in 2013. Despite the year-over-year increases, we continue to expect a modest revenue ramp until permanent reimbursement is secured in Europe. Total operating expenses during the third quarter of 2014 decreased by approximately 24% to \$5.2 million from \$6.8 million in the same period in 2013. The decrease is



primarily due to a significant reduction in expenses related to the Company's NDA submission to the FDA as well as the Company's overall cost management efforts. Total operating expenses for the nine months was \$16.6 million, down 40% from the \$27.5 million in operating expense recorded during a year ago period.

For the third quarter, operating loss was \$5.1 million compared with an operating loss of \$6.7 million during the same period in 2013. The operating loss for the nine-month period was \$16.0 million as compared to \$27.6 million for the same period in the prior year.

Now, I will turn the call back to Jennifer for final comments.

Jennifer Simpson - Delcath Systems Inc - Interim President, CEO

Thanks Barbra. In closing, the HCC, ICC and Ocular Melanoma trials along with the IITs and the EU registry form a robust clinical development strategy designed to generate data in multiple tumor types. We believe these efforts and the continued commercialization of CHEMOSAT in Europe further increase our potential opportunities to help maximize shareholder value. We are pleased with the progress made over the past few weeks and are focused on executing on the program we have laid out for you today. I look forward to sharing our progress on our major milestones with you on the fourth quarter conference call in early 2015.

With that, let me turn the call over to the operator and open the call for questions.

QUESTION AND ANSWER

Operator

(Operator Instructions)

Michael Polyviou - Delcath Systems Inc - IR

All right. While the operator is reviewing the queue, we will take some of the questions that were submitted to us via email. Again, if you would like submit a question, please send to mpolyviou@evcgroup.com.

The first question: Why did you decide to pursue Ocular Melanoma?

Jennifer Simpson - Delcath Systems Inc - Interim President, CEO

Thanks, Michael. It is important to note that Ocular Melanoma remains an unmet medical need with no current standard of care. We have confidence in the efficacy data that we have seen during the Phase 1, 2 and 3 trials prior, which was strong, and the improved safety data from over 130 patient treatments commercially gives us confidence that we have addressed the FDA's earlier comment.

Additionally, the recent abstracts at ESSO combined with our existing data, further confirm our belief in this program. And after full evaluation, we believe this clinical trial, which is focused on overall survival potentially represents the fastest route to an NDA approval in the U.S. and we look forward to meeting with the FDA to discuss the program.

Michael Polyviou - Delcath Systems Inc - IR

Thank you, Jennifer. We have one more question: What is the prominence of the ESSO Congress and how significant are these three abstracts?

Jennifer Simpson - Delcath Systems Inc - Interim President, CEO

So for those of you that aren't familiar with ESSO, its aim is to advance the science and practice of surgical oncology. They promote high standards in the surgical care arena and management of patients with solid tumors. So I was at last week's ESSO Congress and was encouraged to see over a 1,200 leading clinicians attend. This is

one of the largest number of patients reported for us predominantly using our current device and procedure at the scientific meeting, so we were quite pleased with the presentations.

Michael Polyviou - Delcath Systems Inc - IR

Thank you, Jennifer. There appear to be no questions coming in via the phone line. So we will take a third and final question that came in through the email: Do you expect procedure growth next year to come from existing centers, with surgeons doing more procedures or from new centers coming on?

Jennifer Simpson - Delcath Systems Inc - Interim President, CEO

Thanks, Michael. We expect both. Certainly, growth from our existing centers as clinicians have demonstrated positive result as well as new centers coming on board.

Michael Polyviou - Delcath Systems Inc - IR

All right. Derrick, I don't believe there are any more questions. And we can throw the call back now to Jennifer for her closing remarks.

Jennifer Simpson - Delcath Systems Inc - Interim President, CEO

Thanks, operator. That concludes our call and we thank you all for joining us and we look forward to speaking with you again.

Operator

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

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