

**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): **August 12, 2013 (August 6, 2013)**

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)

566 Queensbury Avenue, Queensbury, New York, 12804
(Address of principal executive offices, including zip code)

(518) 743-8892
(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 August 6, 2013, Delcath Systems, Inc. (the “Company”) hosted a conference call to discuss the Company’s financial results for the 2013 fiscal second quarter ended June 30, 2013 and recent operational highlights. 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: August 12, 2013

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 - Q2 2013 Delcath Systems, Inc. Earnings Conference Call

EVENT DATE/TIME: AUGUST 06, 2013 / 08:30PM GMT

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CORPORATE PARTICIPANTS

Doug Sherk *EVC Group - IR Contact*

Eamonn Hobbs *Delcath Systems - President and CEO*

Graham Miao *Delcath Systems - EVP and CFO*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Quarter Two 2013 Delcath Systems, Incorporated Earnings Conference Call. My name is Ben, and I will be your operator for today.

At this time, all participants are in listen-only mode. We will conduct a Q-and-A session towards the end of this conference. (Operator Instructions)

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

I would now like to turn the call over to Mr. Doug Sherk. Please proceed.

Doug Sherk - EVC Group - IR Contact

Thank you, Ben, and good afternoon, everyone. Thank you for joining us today for this conference call and webcast to provide an update on Delcath's fiscal second quarter 2013 results and 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 US Private Securities Litigation Reform Act of 1995. These statements are subject to certain risk and uncertainties, and actual results could differ materially from those projected in any forward-looking statements.

Factors that could cause actual results to differ are discussed from time to time in the Company's filings with the SEC, including our annual report on Form 10-K and our reports on Form 10-Q and 8-K. These documents are available on the Investor Relations section of our website, and we encourage you to review the material. The Company has no obligation to publicly update or revise these forward-looking statements to reflect the events or circumstances after the date they are made.

Participating on today's call are Eamonn Hobbs, President and Chief Executive Officer, and Graham Miao, Executive Vice President and Chief Financial Officer. Following their opening remarks, we will open the call to questions from analysts and institutional investors. To maximize the time allowed for Q&A, please ask two questions, and if you have additional questions, please re-queue to ask those additional questions. For webcast participants, questions can be submitted electronically via 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.

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

Eamonn Hobbs - Delcath Systems - President and CEO

Thanks, Doug. Good afternoon, everyone, and thanks for joining us today.

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This afternoon, we'll discuss the current plans to advance our clinical development program for Melblez Kit in other cancers beyond the ocular melanoma, and we'll provide an update on clinical adoption of CHEMOSAT in Europe and our progress in laying the ground work for potential long-term commercialization and future revenue growth. Graham will then review our second quarter financial results and provide an update on the availability and use of resources now and in the coming months. Let's get started.

Delcath is committed to establishing CHEMOSAT as a promising new treatment for patients with cancers in the liver, and we remain focused on achieving our main objectives -- one, advancing our clinical development program by investing in trials designed to generate data that will help support potential regulatory approvals for Melblez Kit and clinical adoption of CHEMOSAT in Europe, and, two, executing on initiatives underway that will potentially expand clinical adoption of the CHEMOSAT system and help secure compelling reimbursement for CHEMOSAT procedures in Europe, which we believe will provide a foundation to support long-term commercialization of CHEMOSAT and revenue growth. At the same time, we are continuing efforts to increase our efficiencies and reduce our operating cash use this year.

As we reported in our last call on May 2, 2013, the Oncologic Drug Advisory Committee, or ODAC, voted 16 to 0 with no abstentions that the benefits of treatment with Delcath's Melblez Kit do not outweigh the risks associated with the procedure. The FDA is not bound by the recommendation of the Advisory Committee but will consider the Committee's guidance, that is, as it evaluates the Melblez Kit new drug application. We were obviously disappointed with this outcome and await the completion of the FDA's evaluation and decision regarding our Melblez Kit NDA by the Prescription Drug User Fee Act, or PDUFA, goal date of September 13, 2013.

So now let me update you on our clinical development program.

We are finalizing plans to initiate a staged clinical program to investigate Melblez Kit for first-line treatment of patients with unresectable advanced hepatocellular carcinoma, or HCC, also called primary liver cancer. HCC is the most common primary cancer of the liver, with approximately 749,000 new cases diagnosed worldwide annually. HCC is increasing in incidence rates and remains one of the most difficult tumor types to treat despite recent advances for treatment of the disease, and patients are in need of new options. We believe there are over 100,000 global new cases annually that have an unmet need that would be potentially suitable for a Melblez CHEMOSAT treatment.

Subject to acceptance by the FDA of the proposed protocol, we plan to conduct a single-arm, open-label multi-center Phase 2 clinical trial. Assuming positive results and agreement with the FDA, we intend to immediately proceed with a Phase 3 study following the Phase 2. We'll plan to prepare for the Phase 3 study concurrently with the Phase 2 study. The proposed Phase 2 trial will use the Gen-2 filter and will investigate the efficacy and safety of Melblez treatment in approximately 30 patients with unresectable liver cancer confined to the liver in the United States, Europe, and Asia.

We will be targeting comprehensive cancer centers, some of which were participants in our prior Phase 3 trial or are current active sites. We are very pleased to report that Dr. Yuman Fong, a world-renowned expert in the field of HCC therapy, has agreed to chair the Delcath HCC Clinical Development Study. Dr. Fong is Professor of Surgery at Cornell University Medical College and is Murray F. Brennan Chair in Surgery and Vice Chairman of Technology Development at Memorial Sloan-Kettering Cancer Center in New York. Dr. Fong has spent his entire 20-year career at Sloan focused primarily on cancers of the liver, bile duct, and pancreas. He has pioneered and enhanced a number of the surgical procedures now widely used around the world and is viewed as the standard of care in the industry.

We'll look to our lead investigators to provide input to help finalize our protocol, and we'll prepare an amendment to our IND.

Again, subject to acceptance by the FDA, we expect to start patient enrollment in the Phase 2 study before the end of 2013, which will be an important step in potentially addressing a large unmet medical need. Originally, we had explored conducting a study in second-line liver cancer. After careful discussions with key opinion leaders, we intend to focus on first-line treatment, which we believe will allow more patients to access Melblez as compared to second-line treatment only, which represents a larger market potential for Melblez.

We also believe by first conducting a smaller and quicker Phase 2 proof of concept study, we'll have an opportunity to obtain an interim analysis of the data, which should provide us valuable information on safety and efficacy and will help minimize some of the risk before moving straight into an anticipated larger and lengthier Phase 3 study.

We are excited about the potential role for Melblez in the treatment of HCC given an encouraging efficacy signal seen in the small number of HCC patients from our completed multi-arm Phase 2 trial. In the study, five patients with HCC had confirmed partial responses or durable stable disease. Among these patients, one patient received four treatments, achieved a partial response lasting 12.2 months, and survived 20.5 months. Three other patients with stable disease received three to four treatments with a hepatic progression free survival ranging from 3.4 to 8.1 months and overall survival ranging from 5.2 to 19.9 months.

There was no evidence of extrahepatic disease progression. We believe the observed duration of hPFS and OS, overall survival, in this limited number of patients helps support our clinical rationale and warrants further clinical investigation. As a reminder, the earlier study was conducted with a Gen-1 filter. We'll be using the Gen-2 filter in the HCC studies going forward.

With respect to clinical development plans in Europe, our retrospective data collection trial is currently underway at seven sites in Germany, United Kingdom, Italy, France, and Ireland. Additionally, we are initiating a prospective patient registry in the third quarter, which is designed to prospectively collect data from EU commercial experience.

We are also seeking to build clinical experience by supporting investigator-initiated trials, or IITs, with leading EU opinion leaders that have approached us to support new clinical research. We believe there is strong interest in studying other tumor types beyond ocular melanoma. We also 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 Europe.

Turning to our efforts in Europe, although we did not report revenue for our second quarter, we believe we are continuing to make progress on our initiatives to build clinical adoption and establish reimbursement for CHEMOSAT, the two most critical steps to building the foundation for commercialization and supporting long-term revenue growth.

Clinical adoption in Europe continues to grow, with CHEMOSAT treatments performed during the second quarter in Germany, Italy, The Netherlands, and France.

During the quarter, we completed initial training of additional CHEMOSAT treatment sites, including the prestigious cancer treatment research hospitals in Germany, the University of Heidelberg, Europe's largest hospital, Berlin Charite, and more recently, Palma Majorca in Spain. These hospitals have conducted their first CHEMOSAT procedures, and Heidelberg has already retreated the initial patients.

These centers have treated a variety of cancers in the liver, a majority of which have been ocular or cutaneous melanoma liver metastases but have also included cholangiocarcinoma and liver metastases from pancreatic cancer. To date, 43 patients have received treatment in Europe, and we are seeing a number of retreatments.

Importantly, despite concerns raised by the ODAC panel in the US, interest in Europe is encouraging as physicians continue to adopt the CHEMOSAT procedure and are getting direct experience.

In addition to increasing clinical adoption of CHEMOSAT, we continue to pursue permanent, compelling reimbursement for CHEMOSAT procedures in Europe. I'll take a few minutes now to provide additional background on the reimbursement landscape.

Physicians are key advocates for reimbursement and directly influence reimbursement decisions, so expanding clinical adoption is a prerequisite for gaining interim reimbursement and then ultimately permanent reimbursement.

In 2012, we began to educate physicians in Europe on the clinical benefits of CHEMOSAT treatment for patients with cancer in the liver. As a reminder, prior to introducing CHEMOSAT in Europe, there had been no prior clinical experience with the procedure outside of the United States. We believe that we are beginning to see the results of our education efforts and that enthusiasm for CHEMOSAT is building, as evidenced by support from key opinion leaders, or KOLs, and increased number of sites and procedures. As the number of treatment sites and performed procedures continue to grow, we believe the economic basis to seek permanent reimbursement will be established.

We expect to further support our applications for a permanent reimbursement in Europe with publication of our Phase 3 manuscript, and the study authors have recently informed us that they expect to submit for publication by the end of September. Prior to obtaining permanent reimbursement, we are looking to secure payment for CHEMOSAT procedures through various avenues, which can include specific interim reimbursement programs, new technology payment programs, and existing diagnostic-related reimbursement codes. We've already made some progress towards establishing an interim reimbursement pathway in Germany, Italy, and the UK. For example, after NUB Value 4 status for interim reimbursement of CHEMOSAT procedures was granted in Germany, various hospitals are beginning to see a majority of their individual funding applications approved. We continue to gain physician support in these key markets, which we believe will help support further progress on reimbursement.

To finish up, on Europe, we have seen an increase in CHEMOSAT procedures since May and retreatments have picked up, which we believe is a function of expanding clinical experience, interim funding mechanisms getting established, and clinical buy-in from influential KOLs.

We're pleased with the signs of positive momentum, and we're looking to complete training at a number of additional CHEMOSAT treatment centers in the third quarter of 2013. So it appears we're gaining traction in certain key countries which we believe will support our efforts to secure reimbursement and ultimately revenue.

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 questions. Graham?

Graham Miao - Delcath Systems - EVP and CFO

Thank you, Eamonn.

Good afternoon, everybody. Let me start by discussing Delcath's financial condition.

I am pleased to report that we have continued to reduce our cash spend by increasing operational efficiencies. During the second quarter, our cash spend was \$10.5 million, a reduction of 26% year over year for the same period and a reduction of 7% sequentially from the first quarter of 2013. Importantly, we have met our cash spend guidance of \$9 million to \$12 million for the last two quarters, and we expect to further reduce our quarterly cash spend to \$9 million to \$10 million in the third quarter and \$6 million to \$8 million in the fourth quarter of this year as we continue to focus on increasing efficiencies and allocating resources on key priorities.

Cash and the cash equivalents as of June 30, 2013 were \$32.3 million compared with \$23.7 million at December 31, 2012. During the second quarter, we did not access any of our capital facilities. At June 30, 2013, there was approximately \$24 million available under the CEFF program. In July 2013, the Company raised approximately \$1.8 million before related expenses through the ATM equity offering program. As of early August this year, there was approximately \$48 million remaining under the ATM program.

Turning to the income statement, for the second quarter ended June 30, 2013, there were no reported revenues in the quarter as we continued to face challenges in the reimbursement landscape. As a result, we expect product revenue will be limited until further progress is made on securing compelling reimbursement in Europe. To that end, we continue to focus our efforts on increasing clinical adoption in key cancer centers in Europe, which we believe will help establish reimbursement mechanisms for the CHEMOSAT procedure in our target countries. We believe that this will help support future revenue growth in Europe.

Total operating expenses during the second quarter 2013 decreased by 33% to \$10.3 million from \$15.4 million for the same period in 2012. 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. Operating loss was \$10.6 million, which included a non-cash stock-based compensation expense of \$0.2 million as compared with an operating loss of \$15.3 million, including \$1 million in non-cash stock-based compensation expense in the year-ago period.

In summary, we have reduced the costs during the first half of the year and are examining additional expense reduction strategies while focusing resources on our clinical development programs and a clinical adoption which we believe will help drive future revenue growth.

With that, let me turn the call to the operator. We would like to open the call for questions.

QUESTION AND ANSWER

Operator

Thank you very much. (Operator Instructions)

Doug, your first question appears to be from a webcast participant. Please go ahead.

Doug Sherk - EVC Group - IR Contact

Eamonn, when do you expect Phase 2 HCC clinical trials to start, and how long do you expect it to take?

Eamonn Hobbs - Delcath Systems - President and CEO

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Assuming that we get agreement from FDA on the Phase 2 trial design, our goal would be to enroll our first patient prior to the end of this calendar year, and based on our enrollment -- patient enrollment forecast, we anticipate that we would potentially have a positive signal from the trial in the second half of 2014 and the trial would be fully completed in the middle of 2015.

Doug Sherk - EVC Group - IR Contact

We appear to have another question from the webcast.

Eamonn, are you planning on supporting an IIT in the Netherlands?

Eamonn Hobbs - Delcath Systems - President and CEO

Yes, we are. Although it's a bit unusual to discuss investigator-initiated trials at an early stage, we were made aware of the Leiden University posting on their website or a government website their intention to run an investigator-initiated trial on colorectal mets in the liver being treated with our system, which is something we've had under discussion with them for quite some time.

So we're very excited to work with the University of Leiden and that team. They are very interested in developing CHEMOSAT for use in colorectal patients, and considering the large patient population affected by liver metastases that have primary colorectal disease, this could be a very, very exciting development.

Operator

Thank you very much. We now have a third question from via the webcast.

Doug Sherk - EVC Group - IR Contact

Eamonn, can we get an update on Australia and England?

Eamonn Hobbs - Delcath Systems - President and CEO

Australia and England.

In England, we have the UK. We have active procedures being conducted in ocular melanoma primarily, and we are pursuing reimbursement throughout the UK.

In Australia, we have an approval. We have been working with a distributor that has been evaluating the market potential there, and we have yet to get any conclusions from them.

Operator

Thank you. At this time, we still have no further audio questions in the queue and we have no further questions on the webcast either.

Ladies and gentlemen, this concludes the time we have for questions. I would now like to turn the call back over to management for closing remarks.

Eamonn Hobbs - Delcath Systems - President and CEO

Well, thank you, Operator, and thank you, everyone, for joining us today. Thank you for your interest and support.

Operator

Thank you very much for your participation in today's conference, ladies and gentlemen. This concludes the presentation. You may now disconnect. Have a good day.

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