

**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 12, 2013 (November 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)

810 Seventh Avenue, 35<sup>th</sup> 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 6, 2013, Delcath Systems, Inc. (the “Company”) hosted a conference call to discuss the Company’s financial results for the 2013 fiscal third quarter ended September 30, 2013 and recent operational developments. 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.

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**Item 9.01. Financial Statements and Exhibits.**

The following exhibit is filed herewith:

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Delcath Systems, Inc. Conference Call Transcript

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## 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 12, 2013

By: /s/ Peter J Graham  
Name: Peter J. Graham  
Title: Executive Vice President,  
General Counsel

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## EXHIBIT INDEX

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

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# EDITED TRANSCRIPT

DCTH - Q3 2013 Delcath Systems, Inc. Earnings Conference Call

EVENT DATE/TIME: NOVEMBER 06, 2013 / 09:30PM GMT

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## CORPORATE PARTICIPANTS

**Doug Sherk** *EVC Group - IR*

**Jennifer Simpson** *Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, Global Head of Business Operations*

**Graham Miao** *Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, CFO*

## CONFERENCE CALL PARTICIPANTS

**Howard Miller**

## PRESENTATION

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### Operator

Good day, ladies and gentlemen, and welcome to the third quarter 2013 Delcath Systems earnings conference call. My name is Jackie, and I will be your coordinator today.

(Operator Instructions)

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

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

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### Doug Sherk - EVC Group - IR

Thank you, Jackie, 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 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](http://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 Delcath's Interim President and Co-CEOs Jennifer Simpson and Graham Miao. Jennifer is also Delcath's Executive Vice President, Global Head of Business Operations, and Graham Miao is Delcath's Executive Vice President and Chief Financial Officer.

Following their opening remarks, we will open the call to questions from analysts and institutional investors. 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.

And with that I'd like to turn the call over to Jennifer.

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**Jennifer Simpson - Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, Global Head of Business Operations**

Thanks, Doug, and good afternoon, everyone. I am pleased to be joined by Graham Miao, Interim Co-President and Co-CEO, to discuss the path forward that we are charting for Delcath.

This afternoon I'd like to review the focus we are applying to our clinical development program and to driving clinical adoption of CHEMOSAT in Europe. Later I'll turn the call over to Graham, who will review the recent actions we've taken to strengthen the Company, discuss our third quarter financial results and provide an update on the availability and use of resources now and in the coming months.

To begin, since the leadership transition we announced in September we have made significant progress in streamlining our business and increasing our operating efficiencies, actions which were designed to maximize our available resources on two primary goals -- first, advancing our clinical development program by investing in new trials, both Company-sponsored and investigator-initiated studies, or IITs, to generate data that will help support our business; secondly, executing on initiatives already underway that will potentially expand European clinical adoption of the CHEMOSAT system and help secure a compelling reimbursement for the CHEMOSAT procedures in European markets. We believe a focused effort on these priorities will provide a strong foundation to support clinical adoption of CHEMOSAT and the Melphalan Hepatic Delivery System as well as potential revenue growth over the long term.

I'd like to begin with an outline of our current clinical development program.

We are presently finalizing plans for a clinical program to investigate the Melphalan Hepatic Delivery System, which we refer to as Melphalan HDS, for first-line treatment of patients with unresectable advanced hepatocellular carcinoma, or HCC, which is primary liver cancer. In looking at the HCC market, we believe our greatest opportunity for Melphalan HDS is indeed in the first-line setting.

We plan to first conduct a single-arm, open-label, multi-center Phase 2 clinical trial. If these results are favorable, we plan to move directly into a Phase 3 study. The proposed Phase 2 trial will incorporate additional safety measures from the experience that we've gained in the commercial cases as well as the US ocular melanoma program. We'll use the Gen 2 filter and we'll investigate Melphalan HDS in approximately 30 patients with unresectable liver cancer confined to the liver. It will be an international study which will target comprehensive cancer centers that are already familiar with the system. We believe an international study will also support our ongoing commercialization efforts in Europe.

We continue to engage in a dialog with the FDA on our proposed HCC protocol, and we expect to receive written comments from the FDA by year end. From a clinical operations perspective, we have been actively engaging clinical sites to prepare for the initiation of a trial, subject to agreement with the FDA. Based on the anticipated timing of the FDA review and response, we now anticipate to enroll the first patient in this trial during the first quarter of 2014.

The Phase 2 HCC trial aims to assess the overall objective response rate as a primary endpoint, and as secondary endpoints we will look at progression-free survival, or PFS, as well as safety parameters. The trial is also designed to allow us an opportunity to obtain an interim assessment of the data, which we anticipate to be available by the end of 2014. We believe this should provide us with valuable information on safety and efficacy before moving into a Phase 3 study where overall survival would serve as the primary endpoint.

In addition to our HCC trial, we continue to support new clinical research in Europe through investigator-initiated studies. Interest in the therapy's potential remains quite positive, with a number of European key opinion leaders approaching us to support new study proposals in several tumor types across multiple countries. These IITs will help grow clinical experience with CHEMOSAT at key centers throughout Europe.

Turning to ocular melanoma, as we announced in September, on the 13th, the FDA issued a complete response letter on our new drug application for the Melblez Kit for ocular melanoma metastatic to the liver. In their letter the FDA indicated that Delcath will need to perform another well-controlled, randomized clinical study or studies to establish the safety and efficacy of Melblez using overall survival as the primary efficacy outcome measure and which would demonstrate the clinical benefits for the Melblez Kit that outweigh its risks. This trial or trials are to be conducted using the product we intend to market, which is already part of our clinical development program.

We have requested and have been granted a meeting with the FDA to review these and other requirements contained in the letter and will continue to evaluate any potential path forward for the ocular melanoma program.

Our expanded access program was intended to bridge the gap between completion of our melanoma clinical trial and market approval. With market approval of an ocular melanoma indication in the United States now contingent on successful completion of additional trial or trials, we have now closed the EAP. Patients who are

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currently enrolled in the EAP will be able to continue receiving treatment, and Melphalan HDS will be available on a compassionate use basis at centers that obtain institutional review board approval. The system is also available in Europe, where physicians are currently using the system for ocular cases, as well.

I'd like to turn our efforts to Europe, where we are currently pursuing a focused market access approach by seeking interim reimbursement mechanisms for CHEMOSAT procedures in Germany and the United Kingdom, where the clinical adoption of CHEMOSAT has been strongest and the pathway to interim reimbursement is clearest. Additionally, we continue to evaluate various interim reimbursement pathways in other target countries in Europe.

Since launching CHEMOSAT, 14 clinical centers in Europe have used the system to treat patients, and it is being used to treat a variety of cancers in the liver, primarily ocular melanoma with liver metastases as well as HCC, cholangiocarcinoma and liver metastases resulting from colorectal cancer, breast cancer, cutaneous melanoma and additional tumor types. To date, 48 patients have been treated in Europe, and 63 total treatments have been performed.

CHEMOSAT treatments were performed during the third quarter in Germany, Italy, the Netherlands, France and Spain. The University of Heidelberg is one of the recent cancer centers to come onboard and is one of the most prestigious cancer centers in Germany. This center is already acting as an important advocate for the therapy and for reimbursement in the German market.

Obtaining compelling reimbursement for CHEMOSAT procedures in Europe remains our primary objective on the commercialization front. As a reminder, physician use and advocacy drive the reimbursement process, not the Company. Physicians directly influence reimbursement decisions, so expanding the clinical adoption is a prerequisite for gaining interim reimbursement and then ultimately permanent reimbursement.

In Germany we currently have the NUB Value 4 status for interim reimbursement, which allows hospitals to negotiate reimbursement. Centers are currently applying for NUB status for the 2014 year. NUB decisions are expected in the first quarter of 2014, and we are hopeful that Value 1 will be granted for CHEMOSAT procedures, which would mandate reimbursement for those centers that have previously applied.

In the UK, the reimbursement process has been driven by partner centers and their clinical community, with the centers applying for funding for a limited number of patients with ocular melanoma. The mechanism under block funding, if granted, is new, and ongoing policy changes in the National Health Service, or NHS, make it difficult to predict the outcome.

In other target countries in Europe we continue to evaluate various interim reimbursement pathways. We believe these mechanisms will help build the foundation for commercialization and ultimately help support long-term revenue growth.

To conclude on Europe, we continue to see an increase in CHEMOSAT procedures and retreatments, which we believe is a function of expanding clinical experience, interim funding mechanisms getting established and clinical buy-in from influential key opinion leaders. We believe we are making steady progress and will continue our efforts to secure reimbursement and ultimately revenue.

We remain committed to establishing CHEMOSAT and our Melphalan Hepatic Delivery System as a promising new treatment for patients with cancers in the liver.

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?

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**Graham Miao - Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, CFO**

Thank you, Jennifer, and good afternoon, everybody.

Jennifer and I have been working together to develop and implement a number of steps to properly align the Company's management structure, staff levels and the strategic focus necessary to execute our plans and move the Company forward, and we are making progress towards increasing operational efficiencies, reducing our cash spend and strengthening the Company's financial condition.

With that, let me turn to our third quarter results. First and foremost, let me talk about the results of our initiatives to optimize the use of Company's resources. To deal with the challenges of the recent NDA setback we made tough decisions to rightsize our work force commensurate with the Company's priorities and reduce our cost structure to a level that we believe is more sustainable. Cash spend for the quarter was \$6.9 million, a reduction of 53%, or \$7.8 million, year over year for the same period, and a reduction of 34%, or \$3.6 million, sequentially from the second quarter of 2013. Importantly, we have met our cash spend guidance for the last two quarters, and this quarter beat our reduced guidance of \$7 million to \$8 million.

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As part of our efforts, on October 4 we announced the completion of a strategic reorganization, which included the reduction of 21 positions, or 33% of our workforce. We expect the reorganization, in conjunction with other cost-saving measures, to further reduce our quarterly cash spend to \$6 million to \$7 million in the fourth quarter this year and to \$5 million to \$6 million average per quarter next year, 2014, while continuing to ensure resources are optimized and focused on key priorities.

Aside from controlling costs, we raised additional capital by a combination of an equity offering and our ATM program to further strengthen our balance sheet. Combined with October financing activities, our pro forma cash and cash equivalents were approximately \$35 million, instead of the reported \$27.7 million, as of September 30, 2013. We believe these actions together will enable the Company to advance its strategy and extend its cash runway into 2015.

Turning to the income statement, for the third quarter ended September 30, 2013, we recognized \$72,000 in revenue. Now, as we have mentioned previously, we expect the revenue ramp will be slow until compelling reimbursement is secured in Europe.

Total operating expenses during the third quarter 2013 decreased by 44% to \$6.8 million from \$12.2 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.

We have streamlined our Europe operation by resetting and focusing our potential primarily on two countries, Germany and the United Kingdom. These markets, we believe, are -- we have staff on the ground and also have a clearer reimbursement pathway. As Jennifer mentioned, we continue to support potential opportunities for further clinical adoption in other target markets in Europe.

For the third quarter, operating loss was \$6.7 million, which included noncash stock-based compensation income of \$0.2 million due to cancellation of previous stock grants resulting from staff reduction, as compared with an operating loss of \$12.2 million, including \$1.1 million in noncash stock-based compensation expense in the year-ago period.

Before concluding, I want to comment on our intention to maintain NASDAQ listing compliance. The current compliance period expires on December 10, and should it be necessary we intend to request an additional 180-day compliance period from NASDAQ, with a plan to regain compliance.

In summary, we have significantly reduced operating costs and implemented strategies to streamline operations and optimize the use of our resources. We are committed to managing the Company's resources in a more efficient and effective manner. Therefore, we are focused on markets where we believe we have the best chances for success and on clinical programs that we believe will offer us the greatest reward.

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

## QUESTION AND ANSWER

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### Operator

(Operator Instructions)

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### Unidentified Company Representative

Operator, why don't we take a question we have from the webcast participants?

You referenced that you are focusing your efforts on Germany and the UK. Will CHEMOSAT no longer be available or supported in the other EU countries? Won't this limit your opportunities for generating revenue?

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**Jennifer Simpson - Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, Global Head of Business Operations**

Thanks, Michael.

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I think it's important just to clarify, CHEMOSAT continues to be available in the markets that we've been targeting, namely Italy, the Netherlands, Spain, France and Ireland, and we continue to support clinical adoption through investigator-initiated trials in these markets. We're not stopping our efforts in these countries, just taking a more focused approach on the UK and Germany, as we believe these two countries do offer the clearest path for interim reimbursement in the near term.

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**Unidentified Company Representative**

We have another question coming in.

Are you still planning to work with Dr. Yuman Fong as part of the HCC site?

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**Jennifer Simpson - Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, Global Head of Business Operations**

Yes, absolutely. Dr. Fong has agreed to act as the chairman of our HCC program, and, while Memorial Sloan-Kettering won't be an active study site, we are indeed pleased that Dr. Fong will lend his guidance and expertise to the program, which will truly help us move our HCC program as a whole forward. His expertise in diseases related to the liver, specifically liver-targeted local and regional therapy, will be invaluable to us going forward.

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**Unidentified Company Representative**

And we have a third question coming in right now.

Why are you choosing to delay the start of the HCC clinical program by one quarter?

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**Jennifer Simpson - Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, Global Head of Business Operations**

Well, as most of you know, our original plan was to move forward in the second-line space for HCC. And as we looked at the HCC market we believe our greatest opportunity for Melphalan HDS is indeed in the first-line setting. So we made the prudent decision to engage with the FDA on our proposed HCC protocol and expect to have written comments from the FDA by year end. So once we receive those comments we'll incorporate those. We will be looking at a first-quarter start.

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**Unidentified Company Representative**

We have a fourth question, although addressed on the prepared comments.

What are you going to do to address NASDAQ compliance? What's your plan?

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**Graham Miao - Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, CFO**

Thank you for the question. So, as we previously announced, we are in the first 180-day compliance period. Now, if the deficiency is not corrected by December 10, we intend to contact NASDAQ and request an additional 180-day extension. And we would, of course, disclose our plan for regaining compliance at the appropriate time.

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**Operator**

(Operator Instructions)

Howard Miller.

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**Howard Miller**

What are your current plans in moving the corporate headquarters out of the city of New York and either to New Jersey or to Queensbury?

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**Graham Miao - Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, CFO**

Well, we do have a plan, as we announced in the -- earlier in the mid-year that we're looking for a suitable place that the rent is more economical, and but keeping in mind that we have a lease, a committed lease here in New York City and that we have an obligation, so we are looking at different options, making sure that not only the lease here can be covered and through means such as another sublease with appropriate tenant to assume the space. At the same time the space needs to be available in the lower cost place. So there are -- and to your question, yes, we are continuing to look at economic options.

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**Operator**

At this time with no further questions I would like to turn the presentation back to management.

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**Graham Miao - Delcath Systems, Inc. - Interim Co-President and Co-CEO, EVP, CFO**

Thank you, everybody, and we'll keep you updated, and we'll look forward to speaking with you in the next few months, in the next reporting period.

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**Operator**

Ladies and gentlemen, that concludes today's presentation. Thank you for your participation. You may now disconnect, and have a great day.

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