

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): **March 17, 2014 (March 12, 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)

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 March 12, 2014, Delcath Systems, Inc. (the “Company”) hosted a conference call to discuss the Company’s financial results for the fourth quarter and full year ended December 31, 2013 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.

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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: March 17, 2014

By: /s/ Barbra Keck

Name: Barbra Keck

Title: Vice President,  
Controller

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## EXHIBIT INDEX

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

THOMSON REUTERS STREETEVENETS

# EDITED TRANSCRIPT

DCTH - Q4 2013 Delcath Systems, Inc Earnings Conference Call

EVENT DATE/TIME: MARCH 12, 2014 / 08:30PM GMT

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## CORPORATE PARTICIPANTS

**Patty Eisenhour** *EVC Group - IR Contact*

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

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

**Chris Dailey** *EVC Group - IR Contact*

## PRESENTATION

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### Operator

Good day, ladies and gentlemen, and welcome to the Fourth-Quarter 2013 Delcath Systems Incorporated Earnings conference call. My name is Denise, and I will be the operator for today.

(Operator Instructions)

As a reminder, this conference is being recorded for replay purposes. I would now like to turn conference over to Patty Eisenhour.

Please proceed.

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### Patty Eisenhour - EVC Group - IR Contact

Thank you, Denise. Good afternoon, everyone.

Thank you for joining us today for this conference call and webcast to provide an update on Delcath's fiscal fourth-quarter and year-end results for 2013, 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](http://www.delcath.com). The call will also be archived on the company's website.

Before we begin, I would like to remind you that some of the statements made during this conference call will contain forward-looking statements within the meaning of the Safe Harbor provision of the US Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties, and actual results could differ materially from those projected in any forward-looking statements.

Factors that could cause actual results to differ are discussed from time to time in the Company's filings with the SEC, including our annual report on Form 10-K and our reports on Form 10-Q and 8-K. These documents are available on the Investor Relations section of our website, and we encourage you to review the material.

The Company has no obligation to publicly update or revise these forward-looking statements to reflect the events or circumstances after the date they are made.

Participating on today's call are Delcath's interim Co-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 will summarize and address them during the Q&A session.

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And with that, I would like to turn the call over to Jennifer.

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

Thanks, Patty. Good afternoon, everyone.

This afternoon, I would like to provide updates on our two main priorities, our HCC Clinical Development program and CHEMOSAT clinical adoption in Europe.

Later, I will turn the call over to Graham, who will review the continued actions we have taken to strengthen the company, discuss our fourth-quarter and full-year financial results, and provide an update on the availability and use of our resources.

I will begin with an outline of our current Clinical Development program. We are continuing to work on our Clinical Development program to investigate the Mephalan HDS for first-line treatment of patients with unresectable advanced hepatocellular carcinoma, or HCC, also known as primary liver cancer.

We received comments from the FDA at the end of 2013 on our proposed HCC trial protocol and incorporated their comments into our IND submission. We then submitted a supplemental IND to the FDA for this trial in February of 2014.

In addition to the FDA's assessment of the IND, the submitted protocol is now proceeding through a scientific review committee and the institutional review board at our participating institutions. Pending any further comments from the FDA, and clearance of the protocol by our participating institutions, we now anticipate being activated in the second quarter of 2014.

As a reminder, the global HCC Phase II trial program is focused on first-line unresectable advanced hepatocellular carcinoma in approximately 30 patients. The Phase II trial will incorporate additional safety measures from experience gained in our EU commercial cases, as well as the US ocular melanoma program.

The program aims to assess the overall objective response rate, progression free survival, also known as PFS, as well as safety parameters. This study should provide us with valuable information on safety and efficacy before moving into a Phase III study with overall survival as the primary endpoint.

Our priority right now is to help the US and international sites complete the documentation and institutional reviews required in order to activate the trial. Though the February submission of our IND has pushed out the anticipated launch date for our HCC program, we will update investors on the status of our HCC trial on our Q1 2014 call.

In addition to our HCC clinical program, we are also generating clinical data to support adoption of CHEMOSAT in Europe. Last year we completed a retrospective data collection trial, which collected data post hoc from two hospitals in Europe where therapy with the CHEMOSAT system was administered in a non-clinical trial setting.

This provided a retrospective view of hematology results reliably from seven patients treated with the CHEMOSAT system in Europe. While limited and not part of a formal clinical trial design, this retrospective data collection appears to support a reduction in myelosuppression in patients reported anecdotally from commercial centers in Europe.

We are also initiating a patient registry in Europe, which will prospectively collect data from EU commercial cases. The first hospital participating in the registry submitted the protocol to its ethics committee in January 2014, and we anticipate that the first site will begin enrolling patients in the registry in our second quarter.

We believe that the registry will provide valuable safety data and potential signals in various tumor types from a commercial setting, which we believe can be used to support our efforts for clinical adoption and commercialization in Europe.

In addition to the retro and prospective data collection, we are also supporting investigator initiated trials or, IITs, as suitable opportunities present. Presently two IITs -- one in HCC at JWG Hospital in Frankfurt, Germany, and another in colorectal cancer liver metastases at Leiden University Medical Center in the Netherlands -- are nearing activation.

We believe these IITs will serve to build clinical experience at key cancer centers and provide data that will further support efforts to obtain reimbursement in Europe.



Beyond data generation, our immediate commercialization efforts are primarily focused on Germany and the UK. Markets which represent a majority of the total potential liver cancer market, both primary metastatic in the EU and where progress in securing reimbursement for CHEMOSAT treatments offers the best near term opportunities.

Obtaining reimbursement for CHEMOSAT procedures in Europe remains our primary objective on the commercialization front. As a reminder, physician use and advocacy are key drivers of the reimbursement process.

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

In 2013, physicians and patients in Germany submitted individual funding requests, or IFRs, seeking reimbursement for the treatment of liver metastases with the CHEMOSAT system. IFRs are a case-by-case appeal for reimbursement made to the patient's insurance carrier.

While each IFR is evaluated independently, we have been advised that the majority of these applications have been approved in recent months. We expect the IFRs to be the key reimbursement vehicle in the German market in 2014.

In January, we announced that we were again granted NUB Value 4 status for 2014 interim reimbursement in Germany, which provides hospitals the opportunity to negotiate a budget to fund the CHEMOSAT procedures with their regional insurance carriers.

The CHEMOSAT application was submitted by 71 hospitals in Germany, which represents a significant increase in the level of institutional support the procedure received over 2013.

It is important to note that for 2014 reimbursement, a total of 618 medical procedures were submitted to InEK, the German reimbursement authority, for consideration under the NUB scheme, with only 16% of procedures receiving Value 1 status and 6% of the procedures receiving Value 4.

The remaining 78% of procedures were denied coverage or unevaluated, which we believe illustrates how challenging the reimbursement environment is for new procedures in Germany.

InEK first established NUB Value 4 status for CHEMOSAT procedures in 2013, though we have been advised that hospitals performing the CHEMOSAT procedure did not successfully negotiate reimbursement budgets for CHEMOSAT during the year. In 2014, we believe that a number of hospitals performing the procedure intend to pursue reimbursement under Value 4 status.

Remember, NUB is an annual process, and participating centers are required to apply each year for subsequent coverage under the NUB scheme.

Turning to 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.

We currently expect decisions on block grants to be made in the third quarter of 2014 and potential funding, if granted, to be available in the fourth quarter 2014.

The current application seeks funding for 50 to 75 ocular melanoma patients, and 15 to 20 cutaneous melanoma patients. 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 the block grant funding.

Though Germany and the UK are our primary focus, we continue to support clinical adoption of CHEMOSAT in other EU markets where we have established a footprint. During our fourth quarter, CHEMOSAT treatments were performed in Germany, Italy, the Netherlands and Spain.

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

Since launching CHEMOSAT, 17 clinical centers in Europe have used the system to treat patients. These centers have treated 61 patients and have performed a total of 89 treatments.

We are pleased to see an increase in the number of patients receiving repeat treatments at centers that have been able to secure an interim source of funding. Physicians at these centers are observing a beneficial response in patients that have received repeat treatment cycles.

Since November, three more clinical centers have come on board. SPIRE, in Southampton UK, is one of the most recent cancer centers to begin performing procedures, and as our first private hospital treating patients in the UK, acts as an important access point for patients being funded by the large private healthcare sector in the UK.

Private hospital treatments are funded entirely by either private health insurance companies or self-paying patients and, as such, are independent of the National Public Reimbursement System.

University of Leiden Medical Center also performed its first cases, and its CHEMOSAT team is fully trained in the procedure and is ready to begin its IIT in the near-term. Jena University Hospital in Germany also began performing procedures in our fourth quarter.

To conclude on Europe, we continue to see an increase in CHEMOSAT procedures and re-treatments, which we believe is a function of expanding clinical experience, interim funding mechanisms getting established, and clinical buy-ins from influential key opinion leaders.

With that, I would like to turn the call over to Graham Miao for a review of our financial results; and then we will take questions.

Graham?

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

Thank you, Jennifer. Good afternoon, everybody.

I am pleased to report that we continue to make progress on our efforts to enhance operational efficiencies, reduce our cash spend, and strengthen Delcath's financial condition.

Cash spend for the fourth quarter was \$6.2 million. This was a reduction of 36%, or \$3.5 million, year over year for the same period and a reduction of 10%, or \$0.7 million, sequentially from the third quarter of 2013.

Importantly, we have met our cash spend guidance for the last three quarters, and this quarter was at the low-end of our reduced guidance of between \$6 million to \$8 million.

For the full-year, cash used in operating activities was \$34.1 million, a 32% reduction compared to \$50.0 million in the comparable period in 2012. The decrease in cash utilization was in part due to a reduction in NDA-submission-related costs and improved organizational and operational efficiencies.

In conjunction with other cost-saving measures, we remain on target to further reduce our average quarterly cash spend to between \$5 million to \$6 million in 2014.

In addition to controlling costs, we raised additional capital to further strengthen our balance sheet.

In 2013, we raised approximately \$43.2 million before related expenses, including approximately \$26.7 million through the Company's At-the-Market equity offering program, \$9 million through its Committed Equity Financing Facility program, and approximately \$7.5 million through a registered direct offering.

As a result, cash and cash equivalents as of December 31, 2013, were \$31.2 million compared with \$23.7 million at December 31, 2012.

During the first quarter through February 28, 2014, we raised approximately \$4.5 million before related expenses through our At-the-Market offering program. As of February 28, 2014, cash and cash equivalents were \$32.7 million, including \$0.4 million in accounts receivable collection.

We believe that the actions that we have taken will enable the Company to advance its strategy and extend its cash runway through the first half of 2015.

Turning to the income statement, for the fourth quarter ended December 31, 2013, we recognized \$0.3 million in revenue. As we have mentioned previously, we expect the revenue ramp will be slow until reimbursement is secured in Europe.

Total operating expenses during the fourth quarter 2013 decreased by 52%, to \$5.8 million, from \$12 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. The reduction also reflects our more streamlined EU operations.

For the full-year ended December 31, 2013, total revenue was approximately \$0.8 million, of which \$0.3 million was related to the recognition of previously-deferred revenue. Total operating expenses for 2013 decreased by approximately 38%, to \$33.3 million, from \$54.2 million in 2012.

For the fourth quarter, operating loss was \$5.5 million, which included non-cash stock-based compensation income of \$0.3 million due to cancellation of previous stock grants resulting from staff reduction. As compared with an operating loss of \$11.8 million, including \$0.9 million in non-cash stock-based compensation expense in the year ago period.

Operating loss for the full-year was \$33 million, which included \$0.3 million in non-cash stock-based compensation expense, as compared with an operating loss of \$53.9 million, including \$3.8 million in non-cash stock-based compensation expense in 2012.

Before concluding, I want to comment on our intention to maintain NASDAQ listing compliance. We continue to evaluate options to achieve compliance with NASDAQ listing requirements. The current compliance period extension expires on June 9 this year.

On February 24, 2014, we obtained shareholder approval for our Board to effect a reverse stock split within a range from 1 for 8 to 1 for 16, inclusive. The Board is in the process of determining appropriate timing and the ratio of any proposed reverse split in order to regain NASDAQ listing compliance with the minimum bid requirement.

The Board also believes a reverse stock split will provide us with resources and the flexibility, with respect to our capital, sufficient to execute our business plans and strategy.

In summary, we continue to look to optimize our use of resources and expect to maintain our streamlined operations in an efficient and effective manner by focusing on markets where we believe we have the best chances for success, and on clinical programs that we believe will offer us the greatest potential 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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### Patty Eisenhour - EVC Group - IR Contact

Chris, do we have questions in the webcast?

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### Chris Dailey - EVC Group - IR Contact

We have a question from the webcast that reads, you have 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 & Co-CEO, EVP - Global Head of Business Operations

Thanks Chris. Just to clarify CHEMOSAT is available in all countries where it is approved and we continue to support the clinical adoption, and as referenced before through IITs, or investigator initiated trials, we are not stopping our efforts in other countries, just taking a more focused approach on the UK and Germany as these two countries offer the clearest pathway for reimbursement in the near-term.

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**Chris Dailey - EVC Group - IR Contact**

We have another question from the webcast. It reads, I thought you were hoping to initiate patient enrollment by the end of first quarter. Is this delay related to the FDA concerns or institutions you are working with?

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

Thanks Chris. As we mentioned, we made the prudent decision to engage with the FDA on our proposed HCC protocol and we did have a review with the FDA by year-end as originally planned. The FDA provided very productive feedback, as well as our clinical institutions, and we adjusted the protocol accordingly.

So where we are now is, the clinical sites are now submitting the protocol to their scientific review committee as well as the institutional review board at the participating institutions. And subject to any further FDA comments, and also clearance from the institutional review boards, we hope to have the sites open for enrollment in the second quarter.

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**Patty Eisenhaur - EVC Group - IR Contact**

Operator do you want to queue up anymore Q&A for the live calls?

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**Operator**

(Operator Instructions)

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

We want to thank you for participating in today's call. We look forward to updating you during the Q1 2014 call. Thank you.

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**Operator**

Ladies and gentlemen, this replay will be available at 1-888-286-8012 using access code 49674508. This concludes today's conference. You may now disconnect. Have a great day.

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