

**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 13, 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, 35th Floor, New York, New York 10019  
(Address of principal executive offices, including zip code)

(212) 489-2100  
(Registrant's telephone number, including area code)

NONE  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02. Results of Operations and Financial Condition.**

On March 12, 2014, Delcath Systems, Inc. (the “Company”) issued a press release reporting the financial results for the Company’s fiscal fourth quarter and full year ended December 31, 2013 and recent operational developments. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished pursuant to this Current Report on Form 8-K, 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 exhibits are filed herewith:

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release of Delcath Systems, Inc., dated March 12, 2014

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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 13, 2014

By: /s/ Peter J. Graham

Name: Peter J. Graham

Title: Executive Vice President,  
General Counsel

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## EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release of Delcath Systems, Inc., dated March 12, 2014



## DELCATH REPORTS 2013 FOURTH QUARTER AND FULL YEAR RESULTS

– Conference Call and Webcast Today at 4:30 p.m. ET –

**New York, NY – March 12, 2014** – Delcath Systems, Inc. (NASDAQ: DCTH) today reported financial results and operational developments for the fiscal fourth quarter and full year ended December 31, 2013. Developments for the quarter and recent weeks subsequent to quarter end are as follows:

- The Company's cash and cash equivalents increased in the fourth quarter 2013 and the first quarter of 2014; cash position as of February 28, 2014 was \$32.7 million; fourth quarter 2013 cash utilization was \$6.2 million
- 2014 average quarterly cash utilization expected to be between \$5 and \$6 million
- In December 2013 Delcath received comments from FDA on its proposed HCC trial protocol to investigate Melphalan HDS for first-line treatment of patients with unresectable advanced hepatocellular carcinoma (HCC) or primary liver cancer; a supplemental Investigational New Drug (IND) application incorporating FDA comments was submitted to FDA in February 2014; FDA review of the IND is pending
- The Company received the approval from shareholders authorizing its Board of Directors, at its discretion, to effect a reverse stock split of the common stock at a specific ratio within a range from 1-for-8 to 1-for-16, inclusive, on or prior to December 31, 2014

“During our fourth quarter we continued to make steady progress on our main priorities of CHEMOSAT clinical adoption in Europe and our clinical development program for HCC,” commented Jennifer K. Simpson, Interim Co-President and Co-CEO. “We are optimistic that clinical adoption is progressing in Germany and the U.K., key target markets that we believe offer the best near-term revenue opportunities. Experience with CHEMOSAT therapy continues to build, with 89 procedures performed on 61 patients since we first introduced CHEMOSAT in Europe. Concurrently, we had dialogue with the FDA on our supplemental IND submission and with the clinical institutions that will be conducting our HCC studies. As a result of our February IND submission, and assuming scientific review and institutional review board approvals, we now anticipate clinical institutions to become activated in the second quarter of 2014.”

### Financial Results

For the fourth quarter ended December 31, 2013, total revenue was \$0.3 million compared with total revenue of \$0.2 million in the fourth quarter 2012. Operating expenses decreased by approximately 52% to \$5.8 million from \$12.0 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 \$5.5 million, which included non-cash stock-based compensation income of \$0.3 million, 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.

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 decreased by approximately 38% to \$33.3 million from \$54.2 million for the same period in 2012.

Operating loss for the year was \$33.0 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 the year ago period.

In 2013, Delcath raised approximately \$43.2 million before related expenses, including approximately \$26.7 million through the Company's At-the-Market equity offering program, \$9.0 million through its Committed Equity Financing Facility program, and approximately \$7.5 million through a registered direct offering.

Cash and cash equivalents as of December 31, 2013 were \$31.2 million, compared with \$23.7 million at December 31, 2012. During the 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.

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

"During the second half of 2013, we made significant progress in streamlining our business operations and improving our operational efficiencies, while focusing on our key priorities. As a result, we successfully reduced our operating costs and cash burn to more sustainable levels, and we believe we have sufficient resources to execute our plan into the first half of 2015." said Graham G. Miao, Interim Co-President and Co-CEO.

On February 24, 2014, shareholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation authorizing the Board of Directors to affect a reverse stock split of the Company's common stock at a specific ratio within a range from 1-for-8 to 1-for-16, inclusive, on or prior to December 31, 2014. If deemed necessary by the Board, a reverse stock split may enable the Company to regain compliance with NASDAQ's \$1.00 minimum bid price requirement by June 9, 2014, and maintain its listing on the NASDAQ Capital Market.

### **Conference Call and Webcast**

The Company will host a conference call today, March 12, 2014 at 4:30 p.m. ET to discuss its financial results for the fourth quarter and full year of 2013 ended December 31, 2013, and provide an update on recent corporate progress. The dial-in numbers for the conference call are 800-706-7749 (U.S. participants) and 617-614-3474 (international participants); both numbers require passcode 27241849. To access the live webcast, go to the Events & Presentations page on the Investor Relations section of the Company's website at <http://www.delcath.com/investors/events/>.

A taped replay of the call will be available beginning approximately two hours after the call's conclusion and will be available for seven days. Dial-in numbers for the replay are 888-286-8010 and 617-801-6888 for U.S. and International callers, respectively. The replay passcode for both U.S. and International callers is 49674508. An archived webcast will also be available at <http://www.delcath.com/investors/events/>.

### **About Delcath Systems**

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product, the Delcath Hepatic Delivery System, is designed to administer high dose chemotherapy and other therapeutic agents to the liver, while controlling the systemic exposure of those agents. The Company's initial focus is on the treatment of primary and

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metastatic liver cancers. Outside of the United States, our proprietary product to deliver and filter melphalan hydrochloride is marketed under the trade name Delcath Hepatic CHEMOSAT® Delivery System for melphalan hydrochloride. The Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan in April 2012. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT Delivery System for Melphalan in Europe. The Delcath Hepatic Delivery System for Melphalan has not been approved for sale in the United States by the United States Food and Drug Administration. The Company has initiated plans to investigate Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System for primary liver cancer.

*Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This news release contains forward-looking statements, which are subject to certain risks and uncertainties that can cause actual results to differ materially from those described. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the Company's ability to achieve the estimated average quarterly cash utilization for 2014, the impact of the potential reverse stock split and the Company's ability to regain compliance with the NASDAQ Marketplace Rules and maintain its listing on the NASDAQ Capital market, FDA clearance of the Company's IND supplement including the protocol for the Phase II HCC clinical trial and IRB clearance of the same from participating site and the timing of site activation and subject enrollment in the HCC Phase II trial, the timing and results of future clinical trials including without limitation the HCC clinical trial program, the ability of hospitals in Germany to successfully negotiate and receive reimbursement for the CHEMOSAT procedure in their region under Value 4 status and the amount of reimbursement, if any, to be provided under Value 4 status in 2014, approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure, the impact of Value 4 status on potential CHEMOSAT product use and sales in Germany, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK, the Company's ability to successfully commercialize the Melphalan HDS/ CHEMOSAT system and the potential of the Melphalan HDS/CHEMOSAT system as a treatment for patients with primary and metastatic disease in the liver, our ability to obtain reimbursement for the CHEMOSAT system in various markets, the Company's ability to satisfy the requirements of the FDA's Complete Response Letter and provide the same in a timely manner, approval of the current or future Melphalan HDS/CHEMOSAT system for delivery and filtration of melphalan, doxorubicin or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, the Company's ability to successfully enter into strategic partnership and distribution arrangements in foreign markets and the timing and revenue, if any, of the same, uncertainties relating to the timing and results of research and development projects, and uncertainties regarding the Company's ability to obtain financial and other resources for any research, development, clinical trials and commercialization activities. These factors, and others, are discussed from time to time in our filings with the Securities and Exchange Commission. You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking statements to reflect events or circumstances after the date they are made*

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**Contact Information:**

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**DELCATH SYSTEMS, INC.**  
**Consolidated Balance Sheets**  
**as of December 31, 2013 and December 31, 2012**  
**(in thousands, except share data)**

	<b>December 31,</b>	<b>December 31,</b>
	<b>2013</b>	<b>2012</b>
<b>Assets:</b>		
Current assets		
Cash and cash equivalents	\$ 31,249	\$ 23,726
Accounts receivables, net	349	144
Inventories	719	1,105
Prepaid expenses and other current assets	1,711	1,457
Total current assets	<u>34,028</u>	<u>26,432</u>
Property, plant and equipment, net	3,069	4,042
Total assets	<u>\$ 37,097</u>	<u>\$ 30,474</u>
<b>Liabilities and Stockholders' Equity:</b>		
Current liabilities		
Accounts payable	\$ 582	\$ 939
Accrued expenses	3,740	5,790
Warrant liability	2,310	3,427
Total current liabilities	<u>6,632</u>	<u>10,156</u>
Long term liabilities		
Deferred revenue	6	309
Accrued expenses	360	-
Total long term liabilities	<u>366</u>	<u>309</u>
Commitments and contingencies	-	-
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2013 and December 31, 2012	-	-
Common stock, \$.01 par value; 170,000,000 shares authorized; 134,310,337 and 76,849,033 shares issued and 134,282,237 and 76,820,933 shares outstanding at December 31, 2013 and December 31, 2012, respectively	1,343	768
Additional paid-in capital	257,843	218,063
Accumulated deficit	(229,132)	(198,808)
Treasury stock, at cost; 28,100 shares at December 31, 2013 and December 31, 2012	(51)	(51)
Accumulated other comprehensive income	96	37
Total stockholders' equity	<u>30,099</u>	<u>20,009</u>
Total liabilities and stockholders' equity	<u>\$ 37,097</u>	<u>\$ 30,474</u>

**Delcath Systems, Inc.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
**for the three and twelve months ended December 31, 2013 and 2012**  
**(in thousands, except share data)**

	Three months ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Product revenue	\$ 338	\$ 200	\$ 490	\$ 346
Other revenues	-	-	300	-
Total revenue	<u>338</u>	<u>200</u>	<u>790</u>	<u>346</u>
Cost of goods sold	<u>(78)</u>	<u>(39)</u>	<u>(464)</u>	<u>(39)</u>
Gross profit	260	161	326	307
<b>Operating expenses:</b>				
Selling, general and administrative <sup>1</sup>	\$ 3,737	\$ 6,360	\$ 20,657	\$ 27,963
Research and development <sup>1</sup>	2,049	5,626	12,688	26,215
Total operating expenses	<u>5,786</u>	<u>11,986</u>	<u>33,345</u>	<u>54,178</u>
Operating loss	(5,526)	(11,825)	(33,019)	(53,871)
Change in fair value of warrant liability, net	410	1,134	2,756	2,159
Interest income	2	4	20	19
Other expense and interest expense	322	30	(81)	(175)
Net loss	<u>\$ (4,792)</u>	<u>\$ (10,657)</u>	<u>\$ (30,324)</u>	<u>\$ (51,868)</u>
<b>Common share data:</b>				
Basic loss per share	<u>\$ (0.04)</u>	<u>\$ (0.14)</u>	<u>\$ (0.30)</u>	<u>\$ (0.85)</u>
Diluted loss per share	<u>\$ (0.04)</u>	<u>\$ (0.14)</u>	<u>\$ (0.31)</u>	<u>\$ (0.85)</u>
Weighted average number of basic common shares outstanding	<u>120,849,824</u>	<u>74,440,509</u>	<u>100,809,824</u>	<u>61,275,527</u>
Weighted average number of diluted common shares outstanding	<u>120,849,824</u>	<u>74,440,509</u>	<u>105,104,177</u>	<u>61,275,527</u>
<b>Other comprehensive income (loss):</b>				
Foreign currency translation adjustments	\$ (325)	\$ (46)	\$ 59	\$ 37
Comprehensive loss	<u>\$ (5,117)</u>	<u>\$ (10,703)</u>	<u>\$ (30,265)</u>	<u>\$ (51,831)</u>

Note 1:

Includes non-cash stock-based compensation as follows:

	Three months ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Selling, general and administrative	\$ 9	\$ 569	\$ 379	\$ 2,398
Research and development	(305)	334	(88)	1,427
Total stock-based compensation expense	<u>\$ (296)</u>	<u>\$ 903</u>	<u>\$ 291</u>	<u>\$ 3,825</u>