# 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 7, 2014 (August 6, 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, Suite 3505, 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 registran 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)

[] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02. Results of Operations and Financial Condition.

On August 6, 2014, Delcath Systems, Inc. (the "Company") issued a press release reporting the financial results for the Company's fiscal second quarter ended June 30, 2014 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.

Exhibit No.	Description
99.1	Press Release of Delcath Systems, Inc., dated August 6, 2014

### **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.

By: /s/ Peter J. Graham
Name: Peter J. Graham Dated: August 7, 2014

Executive Vice President, General Counsel Title:

# EXHIBIT INDEX

Exhibit No. 99.1

Description
Press Release of Delcath Systems, Inc., dated August 6, 2014



#### For Immediate Release

#### **DELCATH REPORTS 2014 SECOND QUARTER RESULTS**

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

New York, NY – August 6, 2014 – Delcath Systems, Inc. (NASDAQ: DCTH) today reported financial results and operational developments for the fiscal second quarter ended June 30, 2014. Developments for the quarter and recent weeks subsequent to quarter end are as follows:

- · Adoption of CHEMOSAT in Europe continued with 50 treatments performed in the first seven months of 2014, as compared to 22 treatments in the same period of 2013
- · Since initiation of European commercialization, 123 treatments performed on 83 patients as of July 31, 2014
- · Delcath-sponsored Phase 2 study in primary liver cancer (hepatocellular carcinoma or HCC) opened for enrollment at first center in Germany; Johan Wolfgang Goethe University Hospital in Frankfurt
- · Two investigator-initiated clinical trials initiated; Leiden University Medical Center, Leiden, Netherlands enrolls and treats first patient in study of CHEMOSAT to treat liver metastasis in colorectal cancer; Johan Wolfgang Goethe University Hospital in Frankfurt trial open for patient enrollment to study use of CHEMOSAT to treat HCC
- · Second quarter 2014 quarterly net cash utilization of \$4.0 million; Company lowers average cash utilization guidance for the remainder of 2014 to \$4 to \$5 million a quarter; Cash as of June 30, 2014 was \$27.3 million

"We continue to see steady clinical adoption of CHEMOSAT in Europe," commented Jennifer K. Simpson, Interim Co-President & Co-CEO. "As of July 31st of this year, a total of 50 treatments, of which 22 were retreatments, were performed at leading European cancer centers. This compares with 22 treatments and six retreatments during the first seven months of 2013. We believe the growth in performed treatments reflects expanded European clinical experience with CHEMOSAT. Our company-sponsored clinical program for HCC is also moving forward as the first site in Germany is now active and identifying appropriate patients for enrollment. In addition to this first site, Johan Wolfgang Goethe University Hospital in Frankfurt, we expect to add additional German sites, as well as sites in the UK and US during the remainder of 2014. Our goal is to have interim data from the company sponsored Phase 2 studies in the first half of 2015. We are pleased that two leading centers in Europe have opened their investigator initiated trials and believe that data from these trials will support our European efforts and contribute to our clinical program."

#### **Financial Results**

For the second quarter ended June 30, 2014, total product revenue was \$251,000. The company did not record revenue in the yearago second quarter. Operating expenses decreased by approximately 41% to \$6.1 million from \$10.3 million for 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. Operating loss was \$5.9 million during the second quarter, as compared with an operating loss of \$10.6 million in the same period of the prior year.

For the six months ended June 30, 2014, total product revenue was \$561,000, as compared with \$81,000 in the year-ago same period. Operating expenses decreased by approximately 45% to \$11.4 million from \$20.8 million for the first half of 2013. The operating loss for the first six months of 2014 was \$11.0 million as compared with \$20.8 million for the first half of 2013.

Cash and cash equivalents as of June 30, 2014 were \$27.3 million. During the quarter, net cash used in operating activities was \$4.0 million, a 62% reduction compared to \$10.5 million in the comparable period in 2013. The decrease in cash utilization was in part due to a reduction in NDA submission-related costs, and improved organizational and operational efficiencies.

"Our cash utilization, which again was lower than our guidance, demonstrates our continuing efforts to reduce our operational costs and focus on key priorities. Recent expense reduction initiatives include a sublease agreement for 50% of our corporate offices for the remaining lease term of approximately seven years. As a result of this transaction, we expect to achieve total net savings of \$2.6 million over the lease term. In addition, as a result of our successful efforts, we are revising our forecasted average quarterly cash utilization lower to a range of \$4 to \$5 million for the remaining quarters of 2014, as compared to our previous average quarterly cash utilization guidance of \$5 to \$6 million," said Graham G. Miao, Interim Co-President and Co-CEO.

#### **Conference Call and Webcast**

The Company will host a conference call today, August 6, 2014 at 4:30 p.m. ET to discuss its financial results for the second quarter ended June 30, 2014, and provide an update on recent corporate progress.

The dial-in numbers for the conference call are 877-703-6105 (U.S. participants) and 857-244-7304 (international participants); both numbers require passcode: 33935953. 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 93152789. 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 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 U.S. 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 timing of site activation and subject enrollment in the HCC Phase II global clinical trial, the time to complete the HCC Phase II global clinical trial program and the results of the same, the timing and results of future clinical trials including without limitation Company sponsored clinical trials or investigator initiated trials, continued clinical adoption, use and resulting, sales, if any, of the CHEMOSAT system in Europe including the UK and Germany, 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 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.

#### **Contact Information:**

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#### Delcath Systems, Inc.

#### Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2014 and 2013 (Unaudited)

(in thousands, except share and per share data)

	Three months ended June 30,				Six Months Ended June 30,			
	2014		2013		2014		2013	
Product revenue	\$	251	\$	=	\$	561	\$	81
Other revenues		-		-		-		300
Total revenue		251		-		561		381
Cost of goods sold		(66)		(332)		(160)		(363)
Gross profit		185		(332)		401		18
Selling, general and administrative <sup>1</sup>		4,597		6,263		8,416		12,346
Research and development <sup>1</sup>		1,492		3,992		2,949		8,462
Total operating expenses		6,089		10,255		11,365		20,808
Loss from operations		(5,904)		(10,587)		(10,964)		(20,790)
Change in fair value of warrant liability, net		1,297		5,115		1,092		2,842
Interest income		1		5		2		15
Other expense and interest expense		6		(15)		(8)		(395)
Net loss	\$	(4,600)	\$	(5,482)	\$	(9,878)	\$	(18,328)
Loss Per Common Share								
Basic loss per common share*	\$	(0.49)	\$	(0.91)	\$	(1.06)	\$	(3.22)
Diluted loss per common share*	\$	(0.52)	\$	(0.91)	\$	(1.08)	\$	(3.22)
Weighted Average Common Shares								
Weighted average number of basic shares outstanding*		9,426,169		6,023,785		9,363,123		5,683,380
Weighted average number of diluted shares outstanding*		9,480,933		6,023,785		9,462,717		5,683,380
Other Comprehensive Income (Loss)								
Foreign currency translation adjustments	\$	(20)	\$	6	\$	(22)	\$	369
Comprehensive loss	\$	(4,620)	\$	(5,476)	\$	(9,900)	\$	(17,959)

#### Note 1:

Includes non-cash stock-based compensation as follows:

	Three months ended June 30,				Six Months Ended June 30,			
		<u>2014</u>		<u>2013</u>		<u>2014</u>		<u>2013</u>
Selling, general and administrative	\$	84	\$	11	\$	240	\$	529
Research and development		14		140		77		284
Total stock-based compensation expense	\$	98	\$	151	\$	317	\$	813

 $<sup>\*</sup>$  Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.

# Delcath Systems, Inc. Condensed Consolidated Balance Sheets As of June 30, 2014 and December 31, 2013 (Unaudited) (in thousands, per share data)

	June 30, 2014		December 31, 2013		
Assets					
Current assets					
Cash and cash equivalents	\$	27,284	\$	31,249	
Accounts receivables, net		172		349	
Inventories, net		600		719	
Prepaid expenses and other current assets		852		1,711	
Total current assets		28,908		34,028	
Property, plant and equipment, net		2,421		3,069	
Total assets	\$	31,329	\$	37,097	
Liabilities and Stockholders' Equity					
Current liabilities					
Accounts payable	\$	239	\$	582	
Accrued expenses		4,087		3,740	
Warrant Liability		1,075		2,310	
Total current liabilities		5,401		6,632	
Other non-current liabilities		748		366	
Total liabilities		6,149		6,998	
Commitments and contingencies					
Stockholders' equity					
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2014 and December 31, 2013		_		_	
Common stock, \$.01 par value; 170,000,000 shares authorized; 9,451,870 and 8,394,397 shares issued and 9,447,392 and 8,392,641 shares outstanding at June 30, 2014 and December 31, 2013, respectively*		95		84	
Common Stock, to be issued		_		_	
Additional paid-in capital		264,072		259,102	
Accumulated deficit		(239,010)		(229,132)	
Treasury stock, at cost; 1,757 shares at June 30, 2014 and December 31, 2013		(51)		(51)	
Accumulated other comprehensive income		74		96	
Total stockholders' equity		25,180		30,099	
Total liabilities and stockholders' equity	\$	31,329	\$	37,097	

f \* Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.