

**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, 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 2.02. Results of Operations and Financial Condition.

On August 6, 2013, Delcath Systems, Inc. (the “Company”) issued a press release reporting the financial results for the Company’s fiscal second quarter ended June 30, 2013 and recent operational highlights. 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
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99.1	Press Release of Delcath Systems, Inc., dated August 6, 2013
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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: August 7, 2013

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

EXHIBIT INDEX

Exhibit No. **Description**

99.1 Press Release of Delcath Systems, Inc., dated August 6, 2013



DELCATH REPORTS 2013 SECOND QUARTER RESULTS

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

QUEENSBURY, NY – August 6, 2013 – Delcath Systems, Inc. (NASDAQ: DCTH) today reported financial results and operational highlights for the fiscal second quarter and six months ended June 30, 2013. Highlights for the quarter and recent weeks subsequent to quarter end are as follows:

- On May 2, 2013 the *Oncologic Drug Advisory Committee* (ODAC) voted 16-0 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 as it evaluates the Melblez Kit New Drug Application. The *Prescription Drug User Fee Act* (PDUFA) goal date for completion of the FDA's evaluation and decision regarding approval of the Melblez Kit NDA is September 13, 2013.
- The Company plans to initiate a clinical program to investigate Melblez Kit for first-line treatment of patients with unresectable, advanced hepatocellular carcinoma (HCC) or primary liver cancer, Contingent on FDA acceptance.
- Dr. Yuman Fong, Professor of Surgery at Cornell University Medical College and Murray F. Brennan Chair in Surgery and Vice Chairman of Technology Development at Memorial Sloan-Kettering Cancer Center, agreed to serve as study chairman for the Company's clinical development program in HCC.
- Although the Company is encouraged by continued progress in clinical adoption of the Company's Hepatic CHEMOSAT® Delivery System for melphalan in the European Union, it reported no revenue for the second quarter, reflecting challenges in obtaining compelling reimbursement for CHEMOSAT in target countries in the European Union.
- Conducted first CHEMOSAT procedures at the University of Heidelberg, one of Europe's most prestigious cancer treatment research hospitals, Berlin Charite, Europe's largest hospital, and Palma Majorca, Spain, which represented the first CHEMOSAT procedure ever performed in Spain.
- A 33% decrease in total operating expenses to \$10.3 million for the second quarter 2013 as compared to the prior year period. The Company achieved its guidance for quarterly cash utilization during the second quarter. Cash and cash equivalents as of June 30, 2013 were \$32.3 million, compared with \$23.7 million at December 31, 2012.

"Delcath is committed to establishing Melblez Kit and CHEMOSAT as a promising new treatment for patients with cancers in the liver," said Eamonn P. Hobbs, President and CEO. "We remain focused on executing our clinical development plan, while continuing to make progress on our initiatives to build clinical adoption and establish reimbursement for CHEMOSAT in

Europe. During July, we were encouraged by an increasing number of European CHEMOSAT procedures being conducted. Additionally, we have completed training at one of the most prestigious cancer treatment research hospitals in Germany and the largest hospital in Europe as the newest CHEMOSAT treatment sites. We believe our execution on initiatives to expand European clinical adoption and reimbursement will provide a strong foundation for potential long term commercialization of CHEMOSAT and revenue growth.”

“Based on an encouraging efficacy signal seen in patients from the HCC arm of our completed Phase 2 trial at the National Cancer Institute (NCI), we plan to initiate a new global Phase 2 clinical trial for first-line treatment of patients with HCC or primary liver cancer,” continued Mr. Hobbs. “Different from our previous plan to pursue second-line treatment, this new study is expected to get underway in the fourth quarter and is an important step in potentially addressing a large unmet medical need. Importantly, we believe first-line treatment will allow more patients access to Melblez, as compared to second-line treatment only, and represents a larger market potential for Melblez. Following the disappointing ODAC vote, we continue to await the FDA’s decision on our NDA for Melblez™ Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System) for the treatment of patients with unresectable ocular melanoma metastatic to the liver.”

EU Clinical Adoption and Reimbursement

Clinical adoption of the CHEMOSAT procedure in Europe continues to grow, with CHEMOSAT treatments recently performed in Germany, Italy, the Netherlands, France and Spain. Eleven leading European cancer centers are providing CHEMOSAT treatments, with 43 patients treated to date.

In addition to increasing clinical adoption of CHEMOSAT, Delcath continues to pursue permanent, compelling reimbursement for CHEMOSAT procedures in Europe on a country-by-country basis which we believe will help build the foundation for commercialization and help support long-term revenue growth. Prior to obtaining permanent reimbursement, the Company has ongoing initiatives to seek payment for CHEMOSAT procedures through various avenues including specific interim reimbursement programs, new technology payment programs, and existing diagnosis-related group reimbursement codes.

Clinical Development Program

Advanced hepatocellular carcinoma (HCC), or primary liver cancer, is the most common primary cancer of the liver, with approximately 749,000 new cases diagnosed worldwide annually and no effective treatment. Surgical removal is only possible for an estimated 10-20 percent of primary liver cancer patients.

A completed Phase 2 clinical trial of Melblez Kit in the treatment of patients with unresectable liver cancer showed encouraging results in five patients with HCC, including patients with confirmed partial response or durable stable disease.

Delcath is finalizing plans to initiate a staged clinical program to investigate Melblez for first-line treatment of patients with unresectable HCC. Subject to acceptance by the U.S. Food & Drug Administration (FDA), the company will conduct a global, single-arm, open-label, multi-center, Phase 2 clinical trial. Assuming positive results and agreement with FDA, the Phase 2 study will be immediately followed by a Phase 3 study.

Financial Results

For the second quarter ended June 30, 2013, total operating expenses decreased 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 non-cash stock-based compensation expense of \$0.2 million, as compared with an operating loss of \$15.3 million, including \$1.0 million in non-cash stock-based compensation expense, in the year ago period.

For the six months ended June 30, 2013, total revenue was approximately \$0.4 million, of which \$0.3 million was related to the recognition of previously deferred revenue as a result of satisfying certain requirements of the Company's agreement with Chi-Fu Trading Co. Ltd. Total operating expenses for the six months ended June 30, 2013 decreased to \$20.8 million from \$30.0 million for the same period in 2012. Operating loss for the six months ended June 30, 2013 was \$20.8 million, which included \$0.8 million in non-cash stock-based compensation expense, as compared with an operating loss of \$29.9 million, including \$1.9 million in non-cash stock-based compensation expense, in the year ago period.

Delcath raised approximately \$20.9 million before related expenses through the Company's At-the-Market (ATM) equity offering program during the six months ended June 30, 2013. In addition, the Company raised \$9.0 million before related expenses through its Committed Equity Financing Facility (CEFF) program during the six months ended June 30, 2013. At June 30, 2013, there was approximately \$24 million available under the CEFF program. During July 2013, the Company raised approximately \$1.8 million before related expenses through the ATM equity offering program. As of July 31 2013, there was approximately \$48.2 million remaining under the ATM program.

Cash and cash equivalents as of June 30, 2013 were \$32.3 million, compared with \$23.7 million at December 31, 2012. During the six months ended June 30, 2013, cash used in operating activities was \$21.5 million, a 21 percent reduction compared to \$27.2 million in the comparable six-month 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. We believe the Company is on track to meet its previously announced guidance to reduce its quarterly cash burn to \$9-10 million in the third quarter 2013 and \$6-8 million in the fourth quarter of 2013. The Company is examining additional expense reduction strategies, while focusing resources on clinical adoption and development programs.

Conference Call and Webcast

The Company will host a conference call today, August 6, 2013 at 4:30 p.m. ET. The dial-in numbers for the conference call are 866-804-6922 (U.S. participants) and 857-350-1668 (international participants); both numbers require passcode 85959025. 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 21059318. 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. In the U.S., the Company currently has a New Drug Application (NDA) pending with the FDA with a PDUFA goal date of September 13, 2013 for the Melblez Kit for the treatment of patients with unresectable ocular melanoma metastatic to the liver. In addition, the Company has initiated plans to investigate the Melblez Kit for primary liver cancer. For more information, please visit the Company's website at www.delcath.com.

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 impact of the negative advisory vote by the ODAC panel on the FDA's decision regarding the Company's new drug application (NDA), timing of completion of the FDA's review of our NDA, the extent to which the FDA may request additional information, data, or new clinical trials and our ability to provide the same in a timely manner, additional extensions to the PDUFA date by the FDA, acceptability of the Phase 1, 2 and 3 clinical trial data by the FDA, FDA approval of the Company's NDA for the treatment of ocular metastatic melanoma to the liver, adoption, use and resulting sales, if any, in the United States, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe, our ability to successfully commercialize the chemosaturation system and the potential of the chemosaturation 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 timing and results of future clinical trials including without limitation the HCC trials, approval of the current or future chemosaturation 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, our ability to successfully enter into strategic partnership and distribution arrangements in foreign markets including Australia and key Asian markets and timing and revenue, if any, of the same, uncertainties relating to the timing and results of research and development projects,, and uncertainties regarding our 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:

Investors: Financial Media

Michael Polyviou/Patty Eisenhour Chris Gale

EVC Group EVC Group

212-850-6020/951-316-0577 646-201-5431

Delcath Systems, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
for the three and six months ended June 30, 2013 and 2012
(Unaudited)
(in thousands, except share data)

	Three months ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Product revenue	\$ -	\$ 106	\$ 81	\$ 106
Other revenues	-	-	300	-
Total revenue	-	106	381	106
Cost of goods sold	(332)	-	(363)	-
Gross profit	(332)	106	18	106
Operating expenses:				
Selling, general and administrative ¹	6,263	\$ 7,218	\$ 12,346	\$ 14,643
Research and development ¹	3,992	8,204	8,462	15,335
Total operating expenses	10,255	15,422	20,808	29,978
Operating loss	(10,587)	(15,316)	(20,790)	(29,872)
Change in fair value of warrant liability, net	5,115	917	2,842	579
Interest income	5	4	15	7
Other expense and interest expense	(15)	(117)	(395)	(115)
Net loss	\$ (5,482)	\$ (14,512)	\$ (18,328)	\$ (29,401)
Common share data:				
Basic and diluted loss per share	\$ (0.06)	\$ (0.26)	\$ (0.20)	\$ (0.57)
Weighted average number of basic and diluted common shares outstanding	96,380,562	54,847,807	90,934,084	51,582,458
Other comprehensive income (loss):				
Foreign currency translation adjustments	\$ 6	\$ -	\$ 369	\$ -
Comprehensive loss	\$ (5,476)	\$ (14,512)	\$ (17,959)	\$ (29,401)

Note 1:
Includes non-cash stock-based compensation as follows:

	Three months ended June 30,		Three months ended June 30,	
	2013	2012	2013	2012
Selling, general and administrative	\$ 8	\$ 601	\$ 528	\$ 1,163
Research and development	140	352	284	722
Total stock-based compensation expense	\$ 148	\$ 953	\$ 812	\$ 1,885

DEL CATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
as of June 30, 2013 and December 31, 2012
(Unaudited)
(in thousands, except share data)

	<u>June 30,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
Assets:		
Current assets		
Cash and cash equivalents	\$ 32,326	\$ 23,726
Accounts receivables	59	144
Inventories, net	925	1,105
Prepaid expenses and other current assets	1,589	1,457
Total current assets	<u>34,899</u>	<u>26,432</u>
Property, plant and equipment, net	3,507	4,042
Total assets	<u>\$ 38,406</u>	<u>\$ 30,474</u>
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	\$ 705	\$ 939
Accrued expenses	4,270	5,790
Warrant liability	366	3,427
Total current liabilities	<u>5,341</u>	<u>10,156</u>
Deferred revenue	9	309
Commitments and contingencies	-	-
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2013 and December 31, 2012	-	-
Common stock, \$.01 par value; 170,000,000 shares authorized; 96,989,051 and 76,849,033 shares issued and 96,960,951 and 76,820,933 shares outstanding at June 30, 2013 and December 31, 2012, respectively	970	768
Additional paid-in capital	248,867	218,063
Accumulated deficit	(217,136)	(198,808)
Treasury stock, at cost; 28,100 shares at June 30, 2013 and December 31, 2012	(51)	(51)
Accumulated other comprehensive income	406	37
Total stockholders' equity	<u>33,056</u>	<u>20,009</u>
Total liabilities and stockholders' equity	<u>\$ 38,406</u>	<u>\$ 30,474</u>