

**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): **May 9, 2013 (May 8, 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 May 8, 2013, Delcath Systems, Inc. (the “Company”) issued a press release reporting the financial results for the Company’s fiscal first quarter ended March 31, 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
99.1	Press Release of Delcath Systems, Inc., dated May 8, 2013

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: May 9, 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 May 8, 2013



DEL CATH REPORTS 2013 FIRST QUARTER RESULTS

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

QUEENSBURY, NY – May 8, 2013 – Delcath Systems, Inc. (NASDAQ: DCTH) today reported financial results and operational highlights for the fiscal first quarter ended March 31, 2013. Highlights for the quarter and recent weeks are as follows:

First Quarter Financial Results

For the three months ended March 31, 2013, Delcath recorded revenue of 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 Research and Distribution agreement with Chi-Fu Trading Co. Ltd. in Taiwan. The remainder of the revenue was related to product sales. Operating loss was \$10.2 million, which included approximately \$0.7 million in non-cash stock-based compensation expense, as compared with an operating loss of \$14.6 million, including \$0.9 million in non-cash stock-based compensation expense, in the year ago period. Selling, general and administrative (SG&A) expenses in the first quarter of 2013 decreased to \$6.1 million from \$7.4 million for the same period in 2012. Research and development (R&D) expenses for the first quarter decreased to \$4.5 million from \$7.1 million for the same period in 2012. The decrease is primarily due to a significant reduction in expenses related to the Company's New Drug Application (NDA) submission to the FDA, as well as the Company's overall cost management efforts.

Delcath raised approximately \$20.9 million before related expenses through the Company's At-the-Market (ATM) equity offering program during the first quarter of 2013. In addition, the Company raised \$9.0 million before related expenses through its Committed Equity Financing Facility (CEFF) program during the quarter. At March 31, 2013, cash and cash equivalents were \$42.8 million, compared with \$23.7 million at December 31, 2012. For the first quarter, cash utilization was \$11.3 million, a 23 percent reduction compared to \$14.7 million in the first quarter of 2012. The decrease in cash utilization was in part due to a reduction in NDA submission related costs and elimination of non-recurring one-time expenses related to the Company's initiating commercialization activities in Europe. The Company is implementing its previously announced program to reduce its quarterly cash burn to approximately \$9-10 million in the second half of 2013, and is examining additional expense reduction strategies.

EU Commercialization Status

During the quarter, the Company continued commercialization of its Delcath Hepatic CHEMOSAT[®] Delivery system for melphalan in the European Union. The first center in the Netherlands was activated, with the first patients treated at the National Cancer Institute in Amsterdam. Revenue ramp was slower than anticipated as the Company continues to pursue permanent, compelling reimbursement for CHEMOSAT procedures in Europe.

ODAC Outcome

On May 2, 2013, the Oncologic Drugs Advisory Committee (ODAC) to the US Food and Drug Administration voted 16 to 0 that the benefits of treatment with Melblez Kit do not outweigh the risks. The Company is disappointed in the results of the ODAC vote and will continue to work with the FDA throughout its ongoing evaluation of the the Company's NDA for the Melblez Kit. It should be noted that the ODAC vote was focused on data generated during the Phase 3 pivotal trial using the Generation One system. The Company disagrees with the FDA characterization of the safety data during the conduct of the clinical trials on several important points: FDA's views related to patient deaths due to treatment, effectiveness of the serious adverse event mitigation measures instituted in the protocol, and FDA's attribution of patient related deaths due to the filter. As a result of the ODAC outcome, the Company is currently evaluating strategies with regard to pursuing approval to market the Melblez Kit in the United States.

Clinical Development Program

During the quarter the Company held a productive discussion with the FDA on a trial design for a Phase 3 clinical trial in patients with hepatocellular carcinoma (HCC). Based on the positive efficacy signal seen during the Company's Phase 2 trial in HCC, and on the market potential in this tumor type, the Company is focusing its Clinical Development Program in this promising area. Subject to agreement with the FDA, the Company expects to begin enrolling patients in this global Phase 3 trial intended for U.S. registration by the end of 2013. The Company also continues to pursue data collection efforts inclusive of safety data via the U.S. Expanded Access Program in metastatic melanoma. Additionally, the Company has initiated a retrospective data collection trial and is initiating a prospective registry in the EU.

Conference Call and Webcast

The Company will host a conference call today, May 8, 2013 at 4:30 p.m. ET. The dial-in numbers for the conference call are 866-515-2908 (U.S. participants) and 617-399-5122 (international participants); both numbers require passcode 78568082. 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 48370318. 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 diseased organs or regions of the body, while controlling the systemic exposure of those agents.

The Company's initial focus is on the treatment of primary and metastatic liver cancers. In 2010, Delcath announced that its randomized Phase 3 clinical trial for patients with metastatic melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival. The Company also completed a multi-arm Phase 2 trial to treat other 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 (CHEMOSAT Delivery System for Melphalan.) 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 October 2012, the Company satisfied all of the requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin hydrochloride injection (CHEMOSAT Delivery System for Doxorubicin). The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company's NDA has been accepted for filing and substantive review by the FDA. 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, adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in the EEA, our ability to successfully commercialize the chemosaturating system and the potential of the chemosaturating system as a treatment for patients with primary and metastatic disease in the liver, market acceptance of the Gen Two CHEMOSAT system and patient outcomes using the same, approval of the current or future chemosaturating 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, the approval of the Hepatic CHEMOSAT Delivery System device to deliver and filter doxorubicin in key Asian markets and patient outcomes using the same, our ability to obtain reimbursement for the CHEMOSAT system, uncertainties relating to the timing and results of research and development projects, uncertainties relating to the timing and results of future clinical trials, and uncertainties regarding our ability to obtain financial and other resources for any research, development 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:

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EVC Group

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Financial Media

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

	Three months ended March 31,	
	2013	2012
Product revenue	\$ 81	\$ -
Other revenues	300	-
Total revenue	<u>381</u>	<u>-</u>
Cost of goods sold	(31)	-
Gross profit	<u>350</u>	<u>-</u>
Operating expenses:		
Selling, general and administrative ¹	\$ 6,083	\$ 7,423
Research and development ¹	4,469	7,131
Total operating expenses	<u>10,552</u>	<u>14,554</u>
Operating loss	(10,202)	(14,554)
Change in fair value of warrant liability, net	(2,272)	(338)
Interest income	10	3
Other expense and interest expense	(381)	-
Net loss	<u>\$ (12,845)</u>	<u>\$ (14,889)</u>
Common share data:		
Basic and diluted loss per share	<u>\$ (0.15)</u>	<u>\$ (0.31)</u>
Weighted average number of basic and diluted common shares outstanding	<u>85,487,606</u>	<u>48,341,670</u>
Other comprehensive income (loss):		
Foreign currency translation adjustments	\$ 364	\$ -
Comprehensive loss	<u>\$ (12,481)</u>	<u>\$ (14,889)</u>

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

	Three months ended March 31,	
	2013	2012
Selling, general and administrative	\$ 521	\$ 563
Research and development	143	370
Total stock-based compensation expense	<u>\$ 664</u>	<u>\$ 933</u>

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

	March 31, 2013	December 31, 2012
Assets:		
Current assets		
Cash and cash equivalents	\$ 42,804	\$ 23,726
Accounts receivables	81	144
Inventories	1,190	1,105
Prepaid expenses and other current assets	1,667	1,457
Total current assets	45,742	26,432
Property, plant and equipment, net	3,766	4,042
Total assets	<u>\$ 49,508</u>	<u>\$ 30,474</u>
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	\$ 1,511	\$ 939
Accrued expenses	4,078	5,790
Warrant liability	5,485	3,427
Total current liabilities	11,074	10,156
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 March 31, 2013 and December 31, 2012	-	-
Common stock, \$.01 par value; 170,000,000 shares authorized; 91,212,524 and 76,849,033 shares issued and 91,184,424 and 76,820,933 shares outstanding at March 31, 2013 and December 31, 2012, respectively	912	768
Common stock to be issued	56	-
Additional paid-in capital	248,760	218,063
Accumulated deficit	(211,653)	(198,808)
Treasury stock, at cost; 28,100 shares at March 31, 2013 and December 31, 2012	(51)	(51)
Accumulated other comprehensive income	401	37
Total stockholders' equity	38,425	20,009
Total liabilities and stockholders' equity	<u>\$ 49,508</u>	<u>\$ 30,474</u>