

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): **November 7, 2013 (November 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)

810 Seventh Avenue, 35th Floor, New York, NY 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))

Item 2.02. Results of Operations and Financial Condition.

On November 6, 2013, Delcath Systems, Inc. (the “Company”) issued a press release reporting the financial results for the Company’s fiscal third quarter ended September 30, 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 exhibit is filed herewith:

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Delcath Systems, Inc., dated November 6, 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: November 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 November 6, 2013



DELCATH REPORTS 2013 THIRD QUARTER RESULTS

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

New York, NY – November 6, 2013 – Delcath Systems, Inc. (NASDAQ: DCTH) today reported financial results and operational developments for the fiscal third quarter and nine months ended September 30, 2013. Developments for the quarter and recent weeks subsequent to quarter end are as follows:

- Finalizing plans to initiate a global Phase 2 efficacy and safety study to investigate its Melphalan Hepatic Delivery System (Melphalan HDS) for first-line treatment of patients with unresectable hepatocellular carcinoma (HCC); the U.S. Food & Drug Administration (FDA) granted the Company orphan drug designation for melphalan in the treatment of patients with HCC
- The Company raised approximately \$7.5 million in gross proceeds in an offering of shares of its common stock and warrants to purchase common stock; cash and cash equivalents as of September 30, 2013 were \$27.7 million; combined with October financing activities, pro forma cash and cash equivalents were approximately \$35 million
- The Company completed a reorganization of its operations, reducing headcount by a further 33% and lowering its cash utilization by more than 50% compared to the same quarter in the prior year; the Company expects to reduce operating costs in 2014 by approximately \$10 million compared to 2013, while focusing resources on its clinical development program
- The Company's Board of Directors appointed Jennifer K. Simpson and Graham G. Miao as Interim Co-Presidents and Co-CEOs following the separation of Eamonn P. Hobbs from the Company; a Transition Committee was formed to assist the Board and senior management in implementing a leadership transition plan and its evaluation of potential strategic alternatives for the Company
- Delcath received a complete response letter (CRL) from the U.S. Food & Drug Administration (FDA) regarding the non-approval of the Company's New Drug Application (NDA) for Delcath's 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; the Company is evaluating the requirements contained in the letter, and will review potential regulatory paths forward with the FDA for the indication of ocular melanoma liver metastasis

“The actions we took this quarter were designed to optimize utilization of available resources on continued CHEMOSAT clinical adoption in Europe and our clinical development program for HCC,” commented Jennifer Simpson, Interim Co-President and Co-CEO. “We are currently pursuing a focused market access approach in Europe by seeking interim reimbursement mechanisms for CHEMOSAT procedures in Germany and the United Kingdom, where adoption of CHEMOSAT has been strongest. In addition, we continue to evaluate various interim reimbursement pathways in other target countries in the EU. We believe these mechanisms will help build the foundation for commercialization and help support long-term revenue growth.”

“In looking at the HCC market, we believe our greatest potential opportunity is in the first line setting,” continued Dr. Simpson. “As a result, we have modified our proposed clinical trial accordingly, and will be seeking comments from the FDA. Subject to agreement by the FDA, we now anticipate enrolling our first patient in our HCC Phase 2 trial in the first quarter of 2014.”

Financial Results

For the third quarter ended September 30, 2013, total revenue was \$72,000 compared with total revenue of \$39,000 in the third quarter 2012. Operating expenses decreased by approximately 44% to \$6.8 million from \$12.2 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 \$6.7 million, which included non-cash stock-based compensation income of \$0.2 million, as compared with an operating loss of \$12.2 million, including \$1.1 million in non-cash stock-based compensation expense, in the year ago period.

“During the quarter, the proactive decisions we made have enabled our organization to be more efficient and lowered our cash utilization by 53% compared to the prior year period. We expect that these actions will reduce annual operating costs by approximately \$10 million while preserving our ability to invest in our clinical strategy,” commented Graham Miao, Interim Co-President and Co- CEO. “With our current cash balance, buoyed with the just completed capital raise, we have strengthened our balance sheet, which we believe will allow us to execute our strategy into 2015.”

For the nine months ended September 30, 2013, total revenue was approximately \$452,000, of which \$300,000 was related to the recognition of previously deferred revenue. Total operating expenses for the nine months ended September 30, 2013 decreased by approximately 35% to \$27.6 million from \$42.2 million for the same period in 2012. Operating loss for the nine months ended September 30, 2013 was \$27.5 million, which included \$0.6 million in non-cash stock-based compensation expense, as compared with an operating loss of \$42.0 million, including \$2.9 million in non-cash stock-based compensation expense, in the year ago period.

Delcath raised approximately \$23.2 million before related expenses through the Company’s At-the-Market (ATM) equity offering program during the nine months ended September 30, 2013, including approximately \$2.3 million in the third quarter. As of October 31, 2013, there was approximately \$47 million available under the ATM program. In addition, the Company raised \$9.0 million before related expenses through its Committed Equity Financing Facility (CEFF) program during the nine months ended September 30, 2013. At September 30, 2013, there was approximately \$24 million available under the CEFF program.

Cash and cash equivalents as of September 30, 2013 were \$27.7 million, compared with \$23.7 million at December 31, 2012. Combined with October financing activities, pro forma cash and cash equivalents were approximately \$35 million. During the nine months ended September 30, 2013, cash used in operating activities was \$28.9 million, a 29% reduction compared to \$40.7 million in the comparable nine 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.

With the recently announced reorganization, management believes the Company is on track to meet previously established guidance of \$6-7 million cash burn in the fourth quarter of 2013 and a quarterly average cash burn projection of \$5-6 million in 2014. The Company will continue to examine additional cost effectiveness strategies, while focusing resources on clinical adoption and corporate development programs.

Conference Call and Webcast

The Company will host a conference call today, November 6, 2013 at 4:30 p.m. ET. The dial-in numbers for the conference call are 800-706-7745 (U.S. participants) and 617-614-3472 (international participants); both numbers require passcode 38516673. 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 31858222. 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 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: efficiencies and reduction in cash utilization achieved through September 2013 staff reductions, the leadership transition plan and its impact on the Company, the timing and results of future clinical trials including without limitation the HCC trials, 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 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 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 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 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.

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

	September 30, 2013	December 31, 2012
Assets:		
Current assets		
Cash and cash equivalents	\$ 27,735	\$ 23,726
Accounts receivables	111	144
Inventories, net	963	1,105
Prepaid expenses and other current assets	1,200	1,457
Total current assets	30,009	26,432
Property, plant and equipment, net	3,293	4,042
Total assets	\$ 33,302	\$ 30,474
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	\$ 684	\$ 939
Accrued expenses	3,375	5,790
Warrant liability	863	3,427
Total current liabilities	4,922	10,156
Long Term Liabilities		
Deferred revenue	7	309
Accrued expenses	490	-
Total long term liabilities	497	309
Commitments and contingencies		
	-	-
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2013 and December 31, 2012	-	-
Common stock, \$.01 par value; 170,000,000 shares authorized; 103,318,021 and 76,849,033 shares issued and 103,289,921 and 76,820,933 shares outstanding at September 30, 2013 and December 31, 2012, respectively	1,033	768
Additional paid-in capital	250,821	218,063
Accumulated deficit	(224,341)	(198,808)
Treasury stock, at cost; 28,100 shares at September 30, 2013 and December 31, 2012	(51)	(51)
Accumulated other comprehensive income	421	37
Total stockholders' equity	27,883	20,009
Total liabilities and stockholders' equity	\$ 33,302	\$ 30,474

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

	Three months ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Product revenue	\$ 72	\$ 39	\$ 152	\$ 146
Other revenues	-	-	300	-
Total revenue	<u>72</u>	<u>39</u>	<u>452</u>	<u>146</u>
Cost of goods sold	(23)	-	(386)	-
Gross profit	<u>49</u>	<u>39</u>	<u>66</u>	<u>146</u>
Operating expenses:				
Selling, general and administrative ¹	\$ 4,573	\$ 6,960	\$ 16,919	\$ 21,604
Research and development ¹	2,178	5,254	10,639	20,589
Total operating expenses	<u>6,751</u>	<u>12,214</u>	<u>27,558</u>	<u>42,193</u>
Operating loss	(6,702)	(12,175)	(27,492)	(42,047)
Change in fair value of warrant liability, net	(497)	446	2,345	1,025
Interest income	2	9	18	16
Other expense and interest expense	(9)	(93)	(404)	(204)
Net loss	<u>\$ (7,206)</u>	<u>\$ (11,813)</u>	<u>\$ (25,533)</u>	<u>\$ (41,210)</u>
Common share data:				
Basic and diluted loss per share	<u>\$ (0.07)</u>	<u>\$ (0.18)</u>	<u>\$ (0.27)</u>	<u>\$ (0.72)</u>
Weighted average number of basic and diluted common shares outstanding	<u>100,068,998</u>	<u>67,219,224</u>	<u>94,023,834</u>	<u>56,844,697</u>
Other comprehensive income (loss):				
Foreign currency translation adjustments	\$ 15	\$ 87	\$ 384	\$ 83
Comprehensive loss	<u>\$ (7,191)</u>	<u>\$ (11,726)</u>	<u>\$ (25,149)</u>	<u>\$ (41,127)</u>

Note 1:

Includes non-cash stock-based compensation as follows:

	Three months ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Selling, general and administrative	\$ (159)	\$ 665	\$ 370	\$ 1,828
Research and development	(67)	372	217	1,094
Total stock-based compensation expense	<u>\$ (225)</u>	<u>\$ 1,073</u>	<u>\$ 587</u>	<u>\$ 2,922</u>