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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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, 2012**

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**DELCATH SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-16133**  
(Commission  
File Number)

**06-1245881**  
(IRS Employer  
Identification Number)

**810 Seventh Avenue, 35<sup>th</sup> 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)

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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 7, 2012, Delcath Systems, Inc. (the "Company") issued a press release reporting the financial results for the fiscal 2012 second quarter ended June 30, 2012 and recent corporate 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Delcath Systems, Inc., dated August 7, 2012

**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, 2012

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 7, 2012



**DEL CATH REPORTS SECOND QUARTER 2012 FINANCIAL RESULTS AND HIGHLIGHTS  
RECENT ACCOMPLISHMENTS**

*—Conference Call and Webcast Today at 8:30 a.m. ET—*

**NEW YORK, August 7, 2012**—Delcath Systems (NASDAQ: DCTH) today announced financial results and highlights for its second quarter 2012 ended June 30, 2012 and recent corporate accomplishments.

Highlights for the second quarter 2012 and recent weeks include:

- Recognition of first product revenue in Delcath history
- FDA acceptance of the IND Amendments for use of the Generation 2 filter in the U.S. Expanded Access Program, compassionate use, and future clinical trials
- New drug application (NDA) filing with the FDA for the Company's proprietary chemosaturation system on target for mid-August 2012
- Addition of five leading cancer centers in the EU to the CHEMOSAT® initial launch and training program; a total 13 CHEMOSAT centers have been signed with presence in all seven key target EU markets
- Deployment of Quintiles trained medical science liaisons field force in the key target markets in Europe
- To date 16 CHEMOSAT procedures performed at five EU centers; 13 patients with liver dominant metastases from multiple tumor types have been treated, including cutaneous melanoma, ocular melanoma, gastric cancer, breast cancer and cholangiocarcinoma
- Raised \$21.1 million in net proceeds through a follow on offering to fund operational progress and CHEMOSAT European launch
- Board of Directors strengthened with the addition of pharmaceutical industry veterans Laura A. Brege and Tasos G. Konidaris.

“During the second quarter, we made important progress with the European launch of CHEMOSAT, and generated our first product revenue in the Company's history,” said Eamonn P. Hobbs, President and CEO of Delcath. “We have now signed agreements with 13 leading European Union cancer centers, exceeding our original expectations, and intend to sign additional centers in the coming months. Our medical science liaisons are in the field in our seven target markets educating oncologists on the potential of the CHEMOSAT treatment for their patients with liver dominant disease. To date, patients afflicted with liver metastases from five different types of cancer have been treated with CHEMOSAT. During the remainder of the year, our commercial focus in Europe will be to continue to bring clinical centers on line while we work with referring physicians to expand clinical adoption of the CHEMOSAT system as an important therapeutic option for these patients.

“In the U.S., our New Drug Application (NDA) is on schedule and we expect to submit the file to the FDA by mid-August,” continued Mr. Hobbs. “Our amendments to our Investigational New Drug (IND) application to include Generation 2 in our Expanded Access Program and all future clinical trials and compassionate use cases were accepted by the FDA. Additionally, after consultation with the FDA, we have agreed to include the addition of Generation 2 in our NDA submission as a technical change to the Chemistry, Manufacturing, and Control module.”

For the three months ended June 30, 2012, Delcath’s operating loss was \$15.4 million, which included approximately \$1.0 million in non-cash stock-based compensation expense. Operating loss for the three months ended June 30, 2011 was \$10.5 million, which included approximately \$1.2 million in non-cash stock-based compensation expense. Selling, general and administrative (SG&A) expenses were \$7.2 million for the second quarter of 2012, compared to \$5.2 million for the same period in 2011. The increase was primarily due to an increase in sales, marketing and operational support staff in the EU. Research and development (R&D) expenses were \$8.2 million for the second quarter of 2012, compared to \$5.2 million for the same period in 2011. The increase was primarily due to global regulatory efforts including continued preparation of the NDA submission to the FDA and the training and deployment of third party medical science liaisons.

At June 30, 2012, cash, cash equivalents and certificates of deposit were \$29.3 million, compared to \$30.8 million at December 31, 2011. Gross cash spend in the second quarter 2012 was \$14.2 million, as compared to \$8.2 million in the same period in the prior year. The increase was primarily driven by NDA submission related costs and staff increases in various functions to support EU commercialization. Average monthly operating gross spend was \$4.7 million in the second quarter, a decrease from \$4.9 million in the first quarter of 2012. Following the anticipated NDA submission, Delcath expects average monthly cash spend to decrease to between \$3 million to \$4 million for the fourth quarter of 2012.

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

The Company will host a conference call today, August 7, 2012 at 8:30 a.m. ET. To participate in the live call by telephone, please dial 800-762-8779 for domestic participants and 480-629-9645 for international participants. To access the live webcast, go to the Events & Presentations page on Delcath’s website at <http://www.delcath.com/investors/events/>.

A taped replay of the conference call will also be available beginning approximately two hours after the call’s conclusion and will be available for seven days. This replay can be accessed by dialing 800-406-7325 for domestic callers and 303-590-3030 for international callers, both using passcode 4548817. 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. Delcath’s proprietary system for chemosaturation 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 III 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 II trial to treat other liver cancers. The Company obtained authorization to affix a CE Mark for the Delcath Hepatic CHEMOSAT® delivery system in April 2011 and for the second generation hemofiltration cartridge for CHEMOSAT in April 2012. The right to affix the CE mark allows the

Company to market and sell the CHEMOSAT system in Europe. The Company has not yet received FDA approval for commercial sale of its system in the United States. The Company continues with the preparation of its NDA submission and intends to seek FDA approval for commercial sale of its chemosaturating system with melphalan. For more information, please visit the Company's website at [www.delcath.com](http://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 benefits of the Generation 2 CHEMOSAT system and market acceptance of the same, patient outcomes using the Generation 2 system, the timing of the supply and distribution of the CHEMOSAT system to early launch centers in Europe, the time required to build inventory and establish commercial operations in Europe, adoption, use and resulting sales, if any, for the Hepatic CHEMOSAT delivery system in the EEA, our ability to successfully commercialize the chemosaturating system and the potential of the chemosaturating system as a treatment for patients with terminal metastatic disease in the liver, acceptability of the Phase III clinical trial data by the FDA, our ability to address the issues raised in the Refusal to File letter received from the FDA and the timing of our re-submission of our NDA, re-submission and acceptance of the Company's NDA by the FDA, approval of the Company's NDA for the treatment of metastatic melanoma to the liver, adoption, use and resulting sales, if any, for the chemosaturating system in the United States, approval of the current or future chemosaturating system for other indications, actions by the FDA or other foreign regulatory agencies, our ability to obtain reimbursement for the CHEMOSAT system, our ability to successfully enter into distribution and strategic partnership agreements in foreign markets and the corresponding revenue associated with such foreign markets, uncertainties relating to the results of research and development projects and future clinical trials, the timing and use, if any, of the line of credit from SVB, and our ability to access this facility, 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.*

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**DELCATH SYSTEMS, INC.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**for the Three and Six Months Ended June 30, 2012 and 2011**  
(in thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Revenue	\$ 106	\$ —	\$ 106	\$ —
Cost of sales	—	—	—	—
Gross profit	106	—	106	—
Operating expenses:				
Selling, general and administrative <sup>1</sup>	\$ 7,218	\$ 5,238	\$ 14,643	\$ 9,404
Research and development <sup>1</sup>	8,204	5,248	15,335	8,896
Total operating expenses	15,422	10,486	29,978	18,300
Operating loss	(15,316)	(10,486)	(29,872)	(18,300)
Change in fair value of the warrant liability, net	917	5,027	579	10,992
Interest income	4	—	7	1
Other expense and interest expense	(117)	—	(115)	—
Net loss	\$ (14,512)	\$ (5,459)	\$ (29,401)	\$ (7,307)
Common share data:				
Basic and diluted loss per share	\$ (0.26)	\$ (0.13)	\$ (0.57)	\$ (0.17)
Weighted average number of basic and diluted common shares outstanding	54,847,807	42,988,240	51,582,458	42,971,148
Comprehensive Loss	\$ —	\$ (3,000)	\$ —	\$ (9,000)

Note 1:

Includes non-cash stock-based compensation expense as follows:

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Selling, general and administrative	\$ 601	\$ 774	\$ 1,163	\$ 1,660
Research and development	352	396	722	801
Total stock-based compensation expense	\$ 953	\$ 1,170	\$ 1,885	\$ 2,461



**DELCATH SYSTEMS, INC.**  
**Condensed Consolidated Balance Sheets**  
**as of June 30, 2012 and December 31, 2011**  
**(in thousands, except share data)**

	June 30, 2012	December 31, 2011
<b>Assets:</b>		
Current assets		
Cash and cash equivalents	\$ 29,286	\$ 25,777
Investments—Certificates of deposit	—	4,980
Inventories	516	—
Accounts receivables	102	—
Prepaid expenses and other current assets	1,425	1,231
Total current assets	31,329	31,988
Property, plant and equipment		
Land	154	154
Furniture and fixtures	936	880
Machinery and equipment	1,454	1,371
Computer software and equipment	1,899	1,212
Leasehold improvements	1,574	1,148
	6,017	4,765
Less: accumulated depreciation	(2,211)	(1,512)
Property, plant and equipment, net	3,806	3,253
Total assets	<u>\$ 35,135</u>	<u>\$ 35,241</u>
<b>Liabilities and Stockholders' Equity:</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 7,412	\$ 6,398
Warrant liability	5,915	2,439
Total current liabilities	13,327	8,837
Deferred revenue	300	300
Commitments and contingencies	—	—
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at June 30, 2012 and December 31, 2011	—	—
Common stock, \$.01 par value; 170,000,000 shares authorized; 65,744,017 and 48,237,630 shares issued and 65,715,917 and 48,209,534 shares outstanding at June 30, 2012 and December 31, 2011, respectively	657	482
Additional paid-in capital	197,243	172,613
Retained earnings	(176,341)	(146,940)
Treasury stock, at cost; 28,100 shares at June 30, 2012 and December 31, 2011	(51)	(51)
Total stockholders' equity	21,508	26,104
Total liabilities and stockholders' equity	<u>\$ 35,135</u>	<u>\$ 35,241</u>