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 8, 2012 (November 7, 2012)

DELCATH SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-16133**	**06-1245881**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

810 Seventh Avenue, 35th 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)

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 7, 2012, Delcath Systems, Inc. (the "Company") issued a press release reporting the financial results for the fiscal 2012 third quarter ended September 30, 2012 and recent operational progress. 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 November 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: November 8, 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 November 7, 2012

Exhibit 99.1

DELCATH REPORTS THIRD QUARTER 2012 FINANCIAL RESULTS AND RECENT OPERATIONAL PROGRESS

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

NEW YORK, November 7, 2012 – Delcath Systems (NASDAQ: DCTH) today announced financial results for its third quarter 2012 ended September 30, 2012 as well as recent operational progress.

Highlights for the third quarter 2012 and recent weeks include:

- FDA acceptance of Delcath's New Drug Application (NDA) for its proprietary chemosaturation system with melphalan hydrochloride for injection.
- FDA assignment of a Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013.
- Secured national interim reimbursement in Italy; submitted reimbursement applications for the CHEMOSAT procedure in other key European markets, with positive responses expected in some markets during first quarter of 2013.
- Hosted well attended expert symposiums at the European Society for Medical Oncology Annual Congress and the Cardiovascular & Interventional Radiological Society of Europe Annual Congress
- Executed first European distribution agreements with established distributors in Italy and Spain; received first distributor order for CHEMOSAT kits.
- Approval in Australia for the Generation Two Hepatic CHEMOSAT® Delivery System for use with melphalan hydrochloride.
- Satisfied all requirements to affix the CE Mark to the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin in October, 2012.

"During the past three months, Delcath accomplished several significant milestones that help lay the foundation for realizing the full potential of our system in the U.S., Europe and other markets around the world," said Eamonn P. Hobbs, President and CEO. "FDA acceptance of our NDA and designation of a June 15, 2013 PDUFA goal date are the most important developments in our history, and we look forward to working closely with the Agency throughout the review process with the goal of securing approval of our application. During the quarter we also successfully secured procedure reimbursement in Italy under existing coding, and are pursuing other New Technology Payment programs in Italy, Germany and the United Kingdom that we expect to be in

place in certain markets in early 2013. We also announced CE Marking for our Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin, which provides a regulatory pathway for key Asian Markets. The recent approval of our Generation Two CHEMOSAT system in Australia enhances our opportunity to address a potential market of $50-70 million as we seek an exclusive distributor in this region."

For the three months ended September 30, 2012, Delcath recorded sales of $97,000, $58,000 of which was deferred revenue associated with an initial order from our Italian distributor. Operating loss was $12.2 million, which included approximately $1.0 million in non-cash stock-based compensation expense, as compared with an operating loss of $12.2 million, including approximately $0.9 million in non-cash stock-based compensation expense, in the year ago period. Selling, general and administrative (SG&A) expenses were $7.0 million for the third quarter of 2012, compared to $5.7 million for the same period in 2011. The higher SG&A expense was due primarily due to increased EU commercialization expense. Research and development (R&D) expenses were $5.3 million for the third quarter of 2012, compared to $6.4 million for the same period in 2011. The lower R&D expenses reflect the anticipated lower consulting expenses following the submission of the NDA submitted on August 15, 2012.

At September 30, 2012, cash, and cash equivalents were $28.3 million as compared with $29.3 million as of June 30, 2012 and $30.8 million at December 31, 2011. Gross cash spend in the third quarter 2012 was $14.6 million as compared with $14.2 million in the second quarter. The increase was primarily driven by efforts to prepare submission of the NDA to the FDA and ongoing commercialization efforts in the EU. Average monthly operating gross spend was $4.9 million for the third quarter, comparable with $4.7 million reported in the second quarter. Delcath continues to expect average monthly cash spend to be between $3 million to $4 million for the fourth quarter of 2012.

Conference Call and Webcast

The Company will host a conference call today, November 7, 2012 at 4:30 p.m. ET. To participate in the live call by telephone, please dial 800-299-0148 for domestic participants and 617-801-9711 for international participants; both numbers require passcode 42632846. 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 888-286-8010 for domestic callers and 617-801-6888 for international callers, both using passcode 87111973. 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 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. The Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT® delivery system for melphalan hydrochloride in April 2012. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system for melphalan hydrochloride 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, providing a regulatory pathway for CHEMOSAT with doxorubicin hydrochloride injection for countries in Asia that accept the CE Marking as part of their national regulatory requirements. 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. The Company is seeking approval for its proprietary chemosaturation system with melphalan hydrochloride as a treatment for patients with unresectable metastatic melanoma in the liver. 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: our ability to address the contents of the 74 Day Letter from the FDA, timing of completion of the FDA's review of our NDA, the extent to which the FDA may request additional information or data and our ability to provide the same in a timely manner, 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 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 in the EEA, 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, market acceptance of the Gen Two CHEMOSAT system in Australia and our ability to commercialize the CHEMOSAT system in Australia, patient outcomes using the Generation 2 system, approval of the current or future chemosaturation system for other indications, 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 of the same, the initiation of clinical trials in key Asian markets with the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin and timing and results of the same, approval of the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin in key Asian markets, patient outcomes using the Hepatic CHEMOSAT Delivery System device for intra-hepatic arterial delivery and extracorporeal filtration of doxorubicin, our ability to obtain reimbursement for the CHEMOSAT system, uncertainties relating to the results of research and development projects and 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.

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DELCATH SYSTEMS, INC.
Condensed Consolidated Statement of Operations
for the Three and Nine Months Ended September 30, 2012 and 2011
(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Revenue	$ 39	$ —	$ 146	$ —
Cost of goods sold	—	—	—	—
Gross profit	39	—	146	—
Operating expenses:				
Selling, general and administrative[1]	$ 6,960	$ 5,744	$ 21,604	$ 15,148
Research and development[1]	5,254	6,437	20,589	15,333
Total operating expenses	12,214	12,181	42,193	30,481
Operating loss	(12,175)	(12,181)	(42,047)	(30,481)
Change in fair value of warrant liability, net	446	3,872	1,025	14,864
Interest income	9	1	16	1
Other expense and interest expense	(93)	—	(204)	—
Net loss	$ (11,813)	$ (8,308)	$ (41,210)	$ (15,616)
Common share data:				
Basic and diluted loss per share	$ (0.18)	$ (0.18)	$ (0.72)	$ (0.35)
Weighted average number of basic and diluted common shares outstanding	67,219,224	46,961,123	56,844,697	44,315,838
Other comprehensive income (loss):				
Foreign currency translation adjustments	$ 87	$ —	$ 83	$ —
Unrealized loss on securities	—	(3)	—	(14)
Other comprehensive income (loss), total	87	(3)	83	(14)
Comprehensive loss	$ (11,726)	$ (8,311)	$ (41,127)	$ (15,630)

Note 1:

Includes non-cash stock-based compensation as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
General and administrative	$ 665	$ 525	$ 1,828	$ 2,186
Research and development	372	371	1,094	1,173
Total stock-based compensation expense	$ 1,037	$ 896	$ 2,922	$ 3,359

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

	September 30, 2012	December 31, 2011
Assets:		
Current assets		
Cash and cash equivalents	$ 28,298	$ 25,777
Investments – Certificates of deposit	—	4,980
Inventories	941	—
Accounts receivables	43	—
Prepaid expenses and other current assets	1,440	1,231
Total current assets	30,722	31,988
Property, plant and equipment		
Land	154	154
Building and building improvements	449	—
Furniture and fixtures	969	880
Machinery and equipment	1,435	1,371
Computer software and equipment	2,136	1,212
Leasehold improvements	1,698	1,148
	6,841	4,765
Less: accumulated depreciation	(2,556)	(1,512)
Property, plant and equipment, net	4,285	3,253
Total assets	$ 35,007	$ 35,241
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable and accrued expenses	$ 5,148	$ 6,398
Warrant liability	4,561	2,439
Total current liabilities	9,709	8,837
Deferred revenue	358	300
Commitments and contingencies	—	—
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2012 and December 31, 2011	—	—
Common stock, $.01 par value; 170,000,000 shares authorized; 73,422,008 and 48,237,634 shares issued and 73,393,908 and 48,209,534 shares outstanding at September 30, 2012 and December 31, 2011, respectively	734	482
Additional paid-in capital	212,324	172,613
Accumulated deficit	(188,150)	(146,940)
Treasury stock, at cost; 28,100 shares at September 30, 2012 and December 31, 2011	(51)	(51)
Accumulated other comprehensive income	83	—
Total stockholders' equity	24,940	26,104
Total liabilities and stockholders' equity	$ 35,007	$ 35,241