# 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 8, 2014 (May 7, 2014)**

# 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 May 7, 2014, Delcath Systems, Inc. (the "Company") issued a press release reporting the financial results for the Company's fiscal first quarter ended March 31, 2014 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 exhibits are filed herewith:

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of Delcath Systems, Inc., dated May 7, 2014 |

**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 8, 2014

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 7, 2014 |

**DELCATH REPORTS 2014 FIRST QUARTER RESULTS**

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

**New York, NY – May 7, 2014** – Delcath Systems, Inc. (NASDAQ: DCTH) today reported financial results and corporate developments for the fiscal first quarter ended March 31, 2014. Highlights for the quarter and recent weeks subsequent to quarter end are as follows**:**

- Continued adoption of CHEMOSAT in Europe, with 103 procedures performed on 72 patients to date since the product became commercially available in early 2012
- First quarter 2014 cash utilization of $4.5 million, lower than guidance of $5 to $6 million
- Submission of HCC Phase 2 trial protocols to regulatory authorities in the U.S. and Germany; IND amendment for HCC Phase 2 trial cleared by FDA; a separate HCC Phase 2 trial protocol under review by German health authorities
- Regained compliance with NASDAQ listing rules

"We continue to see CHEMOSAT clinical adoption in Europe, where centers have performed over 100 procedures since the product was first launched two years ago," commented Jennifer K. Simpson, Interim Co-President and Co-CEO. "Regarding our clinical development program, our supplemental IND became effective in March, and protocols for the HCC Phase 2 program are under institutional review in the U.S. and Germany."

**Financial Results**

For the first quarter ended March 31, 2014, total product revenue was $0.3 million compared with total product revenue of approximately $0.1 million in the first quarter 2013. Operating expenses decreased by approximately 50% to $5.3 million from $10.6 million for the same period in 2013. 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 $5.3 million, as compared with an operating loss of $12.8 million.

Cash and cash equivalents as of March 31, 2014 were $31.3 million. During the quarter, cash used in operating activities was $4.5 million, a 59% reduction compared to $10.9 million in the comparable period in 2013. The decrease in cash utilization was in part due to a reduction in NDA submission-related costs, and improved organizational and operational efficiencies. The Company believes it has sufficient resources to execute its plan through the first half of 2015.

During the first quarter, the Company raised approximately $4.5 million before related expenses through its At-the-Market offering program.

"I believe our efforts in the second half of 2013 enabled us to begin 2014 as a more efficient and focused organization. We are pleased to have reduced quarterly cash burn by 59%, and we will continue to evaluate our activities to advance the Company's strategy," said Graham G. Miao, Interim Co-President and Co-CEO.

**Conference Call and Webcast**

The Company will host a conference call today, May 7, 2014 at 4:30 p.m. ET to discuss its financial results for the first quarter ended March 31, 2014, and provide an update on recent corporate progress. The dial-in numbers for the conference call are 800-706-7749 (U.S. participants) and 617-614-3474 (international participants); both numbers require passcode 27241849. 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 49674508. 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 product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan HDS)—is designed to administer high dose chemotherapy to the liver, while controlling the systemic exposure to those agents. The Company's principal focus is on the treatment of primary and metastatic liver cancers. In the United States, the Melphalan/HDS system is considered a combination drug and device product, and is regulated as a drug by the United States Food and Drug Administration (FDA). The Melphalan/HDS system has not been approved for sale in the United States. In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT). In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system. The right to affix the CE mark allows the Company to market and sell the CHEMOSAT system in Europe. The Company has initiated plans to investigate the Melphalan/HDS 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: the Company's ability to achieve the estimated average quarterly cash utilization for 2014, IRB clearance of the Phase II HCC protocol from participating sites and the timing of site activation and subject enrollment in the HCC Phase II trial program, the timing and results of future clinical trials including without limitation the HCC clinical trial program, the ability of hospitals in Germany to successfully negotiate and receive reimbursement for the CHEMOSAT procedure in their region under Value 4 status and the amount of reimbursement, if any, to be provided under Value 4 status in 2014, approval of Individual Funding Requests for reimbursement of the CHEMOSAT procedure, the impact of Value 4 status on potential CHEMOSAT product use and sales in Germany, clinical adoption, use and resulting sales, if any, for the CHEMOSAT system to deliver and filter melphalan in Europe including the key markets of Germany and the UK, the Company's ability to successfully commercialize the Melphalan HDS/ CHEMOSAT system and the potential of the Melphalan HDS/CHEMOSAT 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 Melphalan HDS/CHEMOSAT system for delivery and filtration of melphalan or other chemotherapeutic agents for various indications in the US and/or in foreign markets, actions by the FDA or other foreign regulatory agencies, the Company's 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, our ability to maintain NASDAQ listing, and uncertainties regarding the Company's 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:**


| Investor Contact: | Media Contact: |
| --- | --- |
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| 212-850-6020/951-316-0577 | 212-850-6021 |

**DELCATH SYSTEMS, INC.**
**Condensed Consolidated Balance Sheets**
**as of March 31, 2014 and December 31, 2013**
**(Unaudited)**
**(in thousands, except share data)**

| | March 31, 2014 | December 31, 2013 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 31,254 | $ 31,249 |
| Accounts receivables, net | 181 | 349 |
| Inventories, net | 619 | 719 |
| Prepaid expenses and other current assets | 1,292 | 1,711 |
| Total current assets | 33,346 | 34,028 |
| Property, plant and equipment, net | 2,738 | 3,069 |
| Total assets | $ 36,084 | $ 37,097 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 334 | $ 582 |
| Accrued expenses | 3,476 | 3,740 |
| Warrant liability | 2,399 | 2,310 |
| Total current liabilities | 6,209 | 6,632 |
| Other non-current liabilities | 225 | 366 |
| Total liabilities | 6,434 | 6,998 |
| | | |
| Commitments and contingencies | - | - |
| | | |
| Stockholders' equity | | |
| Preferred stock, $.01 par value; 10,000,000 shares authorized; | | |
| no shares issued and outstanding at March 31, 2014 and December 31, 2013 | - | - |
| Common stock, $.01 par value; 170,000,000 shares authorized; | | |
| 9,433,703 and 8,394,397 shares issued and 9,431,907 and 8,392,641 shares outstanding at March 31, 2014 and December 31, 2013, respectively* | 94 | 84 |
| Additional paid-in capital | 263,923 | 259,102 |
| Accumulated deficit | (234,410) | (229,132) |
| Treasury stock, at cost; 1,757 shares at March 31, 2014 and | | |
| December 31, 2013* | (51) | (51) |
| Accumulated other comprehensive income | 94 | 96 |
| Total stockholders' equity | 29,650 | 30,099 |
| Total liabilities and stockholders' equity | $ 36,084 | $ 37,097 |

* Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.

**DELCATH SYSTEMS, INC.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
**for the three months ended March 31, 2014 and 2013**
**(Unaudited)**
**(in thousands, except share data)**

| | Three months ended March 31, 2014 | 2013 |
|---|---|---|
| REVENUES | | |
| Product revenue | $ 310 | $ 81 |
| Other revenues | - | 300 |
| Total revenues | 310 | 381 |
| COSTS OF SALES | | |
| Cost of goods sold | (93) | (31) |
| Gross profit | 217 | 350 |
| OPERATING EXPENSES | | |
| Selling, general and administrative[1] | $ 3,819 | $ 6,083 |
| Research and development[1] | 1,457 | 4,469 |
| Total operating expenses | 5,276 | 10,552 |
| Loss from operations | (5,059) | (10,202) |
| OTHER INCOME (EXPENSE) | | |
| Change in fair value of warrant liability, net | (205) | (2,272) |
| Interest income | 1 | 10 |
| Other expenses | (15) | (381) |
| Net loss | $ (5,278) | $ (12,845) |
| LOSS PER COMMON SHARE | | |
| Basic and diluted loss per common share * | $ (0.57) | $ (2.40) |
| WEIGHTED AVERAGE COMMON SHARES | | |
| Basic and diluted weighted average common shares outstanding * | 9,300,078 | 5,342,976 |
| OTHER COMPREHENSIVE INCOME (LOSS) | | |
| Foreign currency translation adjustments | $ (2) | $ 364 |
| Comprehensive loss | $ (5,280) | $ (12,481) |

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

| | Three months ended March 31, 2014 | 2013 |
|---|---|---|
| Selling, general and administrative | $ 157 | $ 520 |
| Research and development | 63 | 144 |
| Total stock-based compensation expense | $ 220 | $ 664 |

* Reflects a one-for-sixteen (1:16) reverse stock split effected on April 8, 2014.