

DELCATH SYSTEMS, INC.  
Form 10-Q  
May 07, 2014

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

FORM 10-Q  
(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2014  
or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-16133

DELCATH SYSTEMS, INC.  
(Exact name of registrant as specified in its charter)

Delaware 06-1245881  
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

810 Seventh Avenue, 35<sup>th</sup> Floor New York, NY 10019  
(Address of principal executive offices)

(212) 489-2100  
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  
Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  
Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

As of May 6, 2014, 9,442,197 shares of the Company's common stock, \$0.01 par value, were outstanding.

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DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share data)

	March 31, 2014	December 31, 2013
<b>ASSETS</b>		
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
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
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 (Note 11)	—	—
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.

See accompanying Notes to Condensed Consolidated Financial Statements

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DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three months ended March 31,	
	2014	2013
<b>REVENUES</b>		
Product revenues	\$310	\$81
Other revenues	–	300
Total revenues	310	381
<b>COSTS OF SALES</b>		
Costs of goods sold	93	31
Gross profit	217	350
<b>OPERATING EXPENSES</b>		
Selling, general and administrative	3,819	6,083
Research and development	1,457	4,469
Total operating expenses	5,276	10,552
Loss from operations	(5,059)	(10,202)
<b>OTHER INCOME (EXPENSE)</b>		
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)
<b>LOSS PER COMMON SHARE</b>		
Basic and diluted loss per common share *	\$(0.57)	\$(2.40)
<b>WEIGHTED AVERAGE COMMON SHARES</b>		
Basic and diluted weighted average common shares outstanding *	9,300,078	5,342,976
<b>OTHER COMPREHENSIVE INCOME (LOSS)</b>		
Foreign currency translation adjustments	\$(2)	\$364
Comprehensive loss	\$(5,280)	\$(12,481)

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

See accompanying Notes to Condensed Consolidated Financial Statements

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DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Three months ended March 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$(5,278 )	\$(12,845)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	178	467
Restricted stock compensation expense	42	197
Depreciation expense	249	298
Warrant liability fair value adjustment	205	2,272
Loss on write-downs and disposal of equipment	82	—
Non-cash interest income	—	(2 )
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	419	(248 )
Decrease in accounts receivable	169	85
Decrease (increase) in inventories	99	(97 )
Decrease in accounts payable and accrued expenses	(512 )	(764 )
Decrease in other non-current liabilities	(140 )	(300 )
Net cash used in operating activities	(4,487 )	(10,937)
Cash flows from investing activities:		
Purchase of property, plant, and equipment	—	(34 )
Net cash used in by investing activities	—	(34 )
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of stock options and warrants	4,495	30,018
Net cash provided by financing activities	4,495	30,018
Foreign currency effects on cash	(3 )	31
Net increase in cash and cash equivalents	5	19,078
Cash and cash equivalents:		
Beginning of period	31,249	23,726
End of period	\$31,254	\$42,804
Supplemental non-cash activities:		
Fair value of warrants exercised	\$116	\$214

See accompanying Notes to Condensed Consolidated Financial Statements

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*DELCATH SYSTEMS, INC.*

*Notes to the Condensed Consolidated Financial Statements*

(1) General

The interim Condensed Consolidated Financial Statements of Delcath Systems, Inc. (“Delcath” or the “Company”) for the three months ended March 31, 2014 and 2013 should be read in conjunction with the Consolidated Financial Statements included in the Company’s Annual Report on Form 10-K (“Annual Report”) for the year ended December 31, 2013, which has been filed with the Securities Exchange Commission (“SEC”) and can also be found on the Company’s website (www.delcath.com). In these notes the terms “us”, “we” or “our” refer to Delcath and its consolidated subsidiaries.

On February 24, 2014, shareholders of the Company approved, through a shareholder vote, an amendment to the Company’s Amended and Restated Certificate of Incorporation authorizing the Board of Directors to effect a reverse stock split of Delcath’s common stock at a ratio within a range of one-for-eight (1:8) to one-for-sixteen (1:16). The reverse stock split became effective on April 8, 2014 at which time Delcath’s common stock began trading on the NASDAQ Stock Exchange on a one-for-sixteen (1:16) split-adjusted basis. All owners of record as of the close of the NASDAQ market on April 8, 2014 received one issued and outstanding share of Delcath common stock in exchange for sixteen issued and outstanding shares of Delcath common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares created by the one-for-sixteen exchange were rounded up to the next whole share. The reverse stock split had no impact on the number of common shares authorized or the par value per share of Delcath common stock, which remain 170,000,000 and \$0.01, respectively. All current and prior period amounts related to shares, share prices and earnings per share, presented in these Condensed Consolidated Financial Statements and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.

Description of Business

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.

The Company has incurred losses since inception. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. Management believes that its capital resources are adequate to fund operations through the first half of 2015, but anticipates that additional working capital may be required to continue operations. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of the business. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainties and risks related to product development; regulatory approvals; technology; patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing; marketing and sales experience; and dependence on key personnel.

Basis of Presentation

These interim Condensed Consolidated Financial Statements are unaudited and were prepared by the Company in accordance with generally accepted accounting principles in the United States of America (GAAP) and with the SEC's instructions to Form 10-Q and Article 10 of Regulation S-X. They include the accounts of all entities controlled by Delcath and all significant inter-company accounts and transactions have been eliminated in consolidation.

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DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

The preparation of interim financial statements requires management to make assumptions and estimates that impact the amounts reported. These interim Condensed Consolidated Financial Statements, in the opinion of management, reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the Company's results of operations, financial position and cash flows for the interim periods ended March 31, 2014 and 2013; however, certain information and footnote disclosures normally included in our Annual Report have been condensed or omitted as permitted by GAAP. It is important to note that the Company's results of operations and cash flows for interim periods are not necessarily indicative of the results of operations and cash flows to be expected for a full fiscal year.

## Significant Accounting Policies

A description of our significant accounting policies has been provided in Note 3 Summary of Significant Accounting Policies to the Consolidated Financial Statements included in our Annual Report.

## Recently Adopted Accounting Pronouncements

In March 2013, the FASB issued ASU 2013-05, which permits an entity to release cumulative translation adjustments into net income when a reporting entity (parent) ceases to have a controlling financial interest in a subsidiary or group of assets that is a business within a foreign entity. Accordingly, the cumulative translation adjustment should be released into net income only if the sale or transfer results in the complete or substantially complete liquidation of the foreign entity in which the subsidiary or group of assets had resided, or, if a controlling financial interest is no longer held. The revised standard became effective for fiscal years beginning after December 15, 2013. The Company adopted this guidance effective January 1, 2014. The Company's adoption of this standard did not have a material impact on its consolidated financial statements.

## (2) Inventories

Inventories consist of the following:

	March 31, 2014	December 31, 2013
(in thousands)		
Raw materials	\$ 232	\$ 249
Work-in-process	268	364
Finished goods	119	106
Total inventory	\$ 619	\$ 719

## (3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	March 31, 2014	December 31, 2013
(in thousands)		
Insurance premiums	\$310	\$ 407
Professional fees	75	377
Income tax credits receivable	297	326

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Kits for clinical use	295	287
Other <sup>1</sup>	315	314
Total prepaid expenses and other current assets	\$1,292	\$ 1,711

<sup>1</sup> Other consists of various prepaid expenses and other current assets with no individual item accounting for more than 5% of the total balance at March 31, 2014 and December 31, 2013.

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DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

## (4) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

	March 31, 2014	December 31, 2013
(in thousands)		
Leaseholds	\$1,748	\$ 1,749
Furniture	957	957
Equipment	1,487	1,552
Enterprise hardware and software	2,009	2,143
Buildings and land	603	603
Property, plant and equipment, gross	6,804	7,004
Accumulated depreciation	(4,066)	(3,935 )
Property, plant and equipment, net	\$2,738	\$ 3,069

Depreciation expense for the three months ended March 31, 2014 and 2013 was \$0.2 million and \$0.3 million, respectively.

## (5) Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2014	December 31, 2013
(in thousands)		
Compensation, excluding taxes	\$1,853	\$ 1,866
Deferred rent	483	485
Professional fees	323	360
Other <sup>1</sup>	817	1,029
Total accrued expenses	\$3,476	\$ 3,740

<sup>1</sup> Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at March 31, 2014 and December 31, 2013.

In November 2013, the Board of Directors approved an Employee Retention Program for certain key employees, including the Company's executive officers. The executive officers will be eligible to receive a cash retention bonus payment equal to fifty percent (50%) of their current annual salary if they remain employed by the Company through March 31, 2015. The expense related to this program is being accrued ratably over the required service period and has been included in Accrued expenses on the Condensed Consolidated Balance Sheets and in both Selling, general and administrative and Research and development on the Condensed Consolidated Statements of Operations.

## (6) Restructuring Expenses

During 2013, the Company implemented workforce restructurings to better focus its organizational structure, increase efficiency and concentrate financial resources on its clinical development program and European commercialization activity. This resulted in a total reduction in the Company's workforce by 50 employees. As a result of termination

benefits provided to these employees the Company incurred a total restructuring charge of approximately \$4.0 million related to severance expenses. At March 31, 2014, the remaining restructuring reserve of \$1.4 million is included in Accrued expenses and Other non-current liabilities on the Condensed Consolidated Balance Sheets for \$1.2 million and \$0.2 million, respectively.

The following table provides the total severance expense incurred and payments made by the Company through March 31, 2014 as a result of the workforce restructurings implemented in 2013:

	March 31, 2014
(in thousands)	
Restructuring reserve balance, gross	\$3,974
Restructuring expenses paid	(2,606)
Restructuring reserve balance, net	\$1,368

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DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

(7) Stockholders' Equity

Stock Issuances

Reverse Stock Split

On February 24, 2014, shareholders of the Company approved, through a shareholder vote, an amendment to the Company's Amended and Restated Certificate of Incorporation authorizing the Board of Directors to effect a reverse stock split of Delcath's common stock at a ratio within a range of one-for-eight (1:8) to one-for-sixteen (1:16). The reverse stock split became effective on April 8, 2014 at which time Delcath's common stock began trading on the NASDAQ Stock Exchange on a one-for-sixteen (1:16) split-adjusted basis. All owners of record as of the close of the NASDAQ market on April 8, 2014 received one issued and outstanding share of Delcath common stock in exchange for sixteen issued and outstanding shares of Delcath common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares created by the one-for-sixteen exchange were rounded up to the next whole share. The reverse stock split had no impact on the number of common shares authorized or the par value per share of Delcath common stock, which remain 170,000,000 and \$0.01, respectively. All current and prior period amounts related to shares, share prices and earnings per share, presented in these Condensed Consolidated Financial Statements and the accompanying Notes, have been restated to give retrospective presentation for the reverse stock split.

At-the-Market ("ATM") Programs

In December 2011, the Company entered into an agreement with Cowen and Company, LLC ("Cowen") to sell shares of its common stock, par value \$.01 per share, from time to time, through an ATM equity offering program having aggregate sales proceeds of \$39.8 million, under which Cowen would act as sales agent. During the three months ended March 31, 2013, the Company sold approximately 0.9 million shares of its common stock under this ATM program for proceeds of approximately \$20.9 million, with net cash proceeds after related expenses of approximately \$20.8 million, and successfully completed the program. As of March 31, 2014, there were no shares of common stock of the Company remaining for sale under this ATM program.

In March 2013, the Company entered into a new agreement with Cowen to sell shares of the Company's common stock, par value \$.01 per share, from time to time, through an ATM equity offering program having aggregate sales proceeds of \$50.0 million, under which Cowen will act as sales agent. During the year ended December 31, 2013, the Company sold approximately 1.0 million shares of its common stock under this ATM program for proceeds of approximately \$5.0 million, with net cash proceeds after related expenses of approximately \$4.8 million. During the three months ended March 31, 2014 the Company sold an additional 1.0 million shares of its common stock under this ATM program for proceeds of approximately \$4.4 million, with net cash proceeds after related expenses of approximately \$4.4 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-187230). The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. As of March 31, 2014, the Company has approximately \$40.4 million remaining under the program.

Committed Equity Financing Facility ("CEFF") Program

In December 2012, the Company entered into an agreement with Terrapin Opportunity, L.P. ("Terrapin") for a CEFF program. Under the agreement Terrapin committed to purchase up to \$35.0 million of Delcath common stock over a

24-month term. Since inception, the Company has sold approximately 0.5 million shares of its common stock through the program for total proceeds of approximately \$11.1 million, with net cash proceeds after related expenses of approximately \$10.8 million. As a result, there was approximately \$23.9 million available under this CEFF program as of March 31, 2014. The shares were issued pursuant to an effective registration statement on Form S-3 (333-183675). The net proceeds will be used for general corporate purposes including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and general working capital needs.

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DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

Warrants

In June 2009, the Company completed the sale of 0.1 million shares of its common stock and the issuance of warrants to purchase 0.1 million common shares (the “2009 Warrants”) pursuant to a subscription agreement with a single investor. The Company received proceeds of \$3.0 million, with net cash proceeds after related expenses from this transaction of approximately \$2.7 million. Of those proceeds, the Company allocated an estimated fair value of \$2.2 million to the 2009 Warrants. As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company’s October 2013 sale of common stock and warrants. At March 31, 2014, the 2009 Warrants were exercisable at \$2.56 per share with approximately 40,000 warrants outstanding. The 2009 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. During the three months ended March 31, 2014, 25,000 2009 Warrants were exercised for net proceeds of approximately \$0.1 million.

In May 2012, the Company completed the sale of 1.0 million shares of its common stock and the issuance of warrants to purchase 0.3 million common shares (the “2012 Warrants”) pursuant to an underwriting agreement. The Company received proceeds of \$21.5 million, with net cash proceeds after related expenses from this transaction of approximately \$21.1 million. Of those proceeds, the Company allocated an estimated fair value of \$3.4 million to the 2012 Warrants. As required by the 2012 Warrant agreement, the exercise price of the warrants was adjusted following the Company’s October 2013 sale of common stock and warrants. At March 31, 2014, the 2012 Warrants were exercisable at \$2.56 per share with 0.3 million warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3. During the three months ended March 31, 2014, approximately 13,000 2012 Warrants were exercised for net proceeds of approximately \$34,000.

In October 2013, the Company completed the sale of 1.3 million shares of its common stock and the issuance of warrants to purchase 0.6 million common shares (the “2013 Warrants”) pursuant to a placement agency agreement. The Company received proceeds of \$7.5 million, with net cash proceeds after related expenses from this transaction of approximately \$6.9 million. Of those proceeds, the Company allocated an estimated fair value of \$1.9 million to the 2013 Warrants. The 2013 Warrants will become exercisable at \$7.04 per share on April 30, 2014. The 2013 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3.

Stock Incentive Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the “Plans”) under which 187,500, and 406,250 shares, respectively, have been reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. The Plans are administered by the Compensation and Stock Option Committee of the Board of Directors which determines the individuals to whom awards shall be granted as well as the type, terms, conditions, option price and the duration of each award.

A stock option grant allows the holder of the option to purchase a share of the Company’s common stock in the future at a stated price. Options granted under the Plans vest as determined by the Company’s Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for the three months ended March 31, 2014 is as follows:

Stock Option Activity under the Plans  
 Stock      Exercise

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	Options	Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2013	252,133	\$4.80—\$248.64	\$57.90	7.36
Granted	—	—	—	
Forfeited	(14,304 )	\$7.36—\$248.64	\$109.54	
Expired	—	—	—	
Outstanding at March 31, 2014	237,829	\$4.80—\$248.64	\$54.79	7.13

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DELCATH SYSTEMS, INC.

Notes to the Condensed Consolidated Financial Statements

For the three months ended March 31, 2014 and 2013, the Company recognized compensation expense of approximately \$0.2 million and \$0.5 million, respectively, relating to stock options granted to employees.

There were no options granted during the three months ended March 31, 2014. The estimated fair value of each option award granted during the three month period ended March 31, 2013 was determined on the date of grant using an option pricing model with the following assumptions: