

DELCATH SYSTEMS, INC.
Form 10-Q
May 06, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2015

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 (I.R.S. Employer
incorporation or organization) Identification No.)
1301 Avenue of the Americas, 43FL

(Address of principal executive offices)

(212) 489-2100

(Registrant's telephone number, including area code)

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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 x 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 x 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

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 x

As of May 6, 2015, 12,169,706 shares of the Company's common stock, \$0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

Table of Contents

	Page
<u>PART I—FINANCIAL INFORMATION</u>	
Item 1. Financial Statements (Unaudited)	
<u>Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2015 and 2014</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	26
Item 4. <u>Controls and Procedure</u>	27
<u>PART II—OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	28
Item 1A. <u>Risk Factors</u>	29
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
Item 3. <u>Defaults upon Senior Securities</u>	29
Item 4. <u>Mine Safety Disclosure</u>	30
Item 5. <u>Other Information</u>	30
Item 6. <u>Exhibits</u>	30
<u>SIGNATURES</u>	31

DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets

(in thousands, except share data)

	March 31, 2015 (Unaudited)	December 31, 2014
Assets:		
Current assets		
Cash and cash equivalents	\$ 18,462	\$ 20,469
Accounts receivables, net	312	174
Inventories	274	349
Prepaid expenses and other current assets	982	974
Total current assets	20,030	21,966
Property, plant and equipment, net	1,620	1,798
Total assets	\$ 21,650	\$ 23,764
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	\$ 268	\$ 748
Accrued expenses	3,135	3,603
Warrant liability	836	225
Total current liabilities	4,239	4,576
Other non-current liabilities	987	1,043
Total liabilities	5,226	5,619
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value; 10,000,000 shares authorized; no shares		
issued and outstanding at March 31, 2015 and December 31, 2014,		
respectively		
	—	—
Common stock, \$.01 par value; 170,000,000 shares authorized; 12,200,397 and		
9,740,397 shares issued and 12,169,706 and 9,708,841 shares outstanding		
at March 31, 2015 and December 31, 2014, respectively		
	122	97
Additional paid-in capital	266,349	264,592
Accumulated deficit	(250,002)	(246,513)
Treasury stock, at cost; 1,757 shares at March 31, 2015 and December 31,		
2014, respectively		
	(51)	(51)
Accumulated other comprehensive income	6	20
Total stockholders' equity	16,424	18,145

Total liabilities and stockholders' equity	\$ 21,650	\$23,764
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See accompanying Notes to Condensed Consolidated Financial Statements.

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,	
	2015	2014
Revenue	\$444	\$310
Cost of goods sold	133	93
Gross profit	311	217
Operating expenses:		
Selling, general and administrative	3,040	3,819
Research and development	979	1,457
Total operating expenses	4,019	5,276
Operating loss	(3,708)	(5,059)
Change in fair value of the warrant liability, net	209	(205)
Interest income	2	1
Other income (expense) and interest income (expense)	9	(15)
Net loss	\$(3,488)	\$(5,278)
Other comprehensive income (loss):		
Foreign currency translation adjustments	\$(14)	\$(2)
Comprehensive loss	\$(3,502)	\$(5,280)
Common share data:		
Basic and diluted loss per share	\$(0.32)	\$(0.57)
Weighted average number of basic and diluted common shares outstanding	10,857,142	9,300,078

See accompanying Notes to Condensed Consolidated Financial Statements.

DELCATH SYSTEMS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Three months ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(3,488)	\$(5,278)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	102	178
Restricted stock compensation expense	22	42
Depreciation expense	196	249
Loss on disposal of equipment	—	82
Warrant liability fair value adjustment	(209)	205
Non-cash interest income	(1)	—
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses and other assets	(14)	419
Decrease (increase) in accounts receivable	(156)	169
Decrease (increase) in inventories	65	99
Increase (decrease) in accounts payable and accrued expenses	(877)	(512)
Increase (decrease) in other non-current liabilities	(54)	(140)
Net cash used in operating activities	(4,414)	(4,487)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(45)	—
Net cash (used in) provided by investing activities	(45)	—
Cash flows from financing activities:		
Net proceeds from sale of stock	2,479	4,495
Net cash provided by financing activities	2,479	4,495
Foreign currency effects on cash and cash equivalents	(27)	(3)
Net (decrease) increase in cash and cash equivalents	(2,007)	5
Cash and cash equivalents:		
Beginning of period	20,469	31,249
End of period	\$18,462	\$31,254
Supplemental non-cash activities:		
Fair value of warrants issued	\$820	\$—
Fair value of warrants exercised	\$—	\$116

See accompanying Notes to Condensed Consolidated Financial Statements.

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, 2015 and 2014 should be read in conjunction with the consolidated financial statements included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014 (“Annual Report”), 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 April 8, 2014, the Company effected a one-for-sixteen (1:16) reverse stock split. Refer to Note 7 Stockholders’ Equity of these condensed consolidated financial statements for further information. 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 late-stage clinical development company with early commercial activity in Europe focused on cancers of the liver. We are a specialty pharmaceutical and medical device company developing our proprietary product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS). 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).

Our primary focus is on the execution of our clinical development program (CDP) in ocular melanoma liver metastases (mOM), intrahepatic cholangiocarcinoma (ICC), hepatocellular carcinoma (HCC or primary liver), and certain other cancers that are metastatic to the liver. We believe the disease states we are investigating represent a multi-billion dollar global market opportunity and a clear unmet medical need.

Our clinical development program for CHEMOSAT/Melphalan/HDS is comprised of: a planned Global Phase 3 clinical trial investigating overall survival in ocular melanoma liver metastases, and a Global Phase 2 clinical trial investigating Melphalan/HDS with and without sorafenib in HCC, opened for enrollment in the fall of 2014. We expect to expand the Global Phase 2 HCC trial to include a cohort of patients with ICC. Our CDP also includes sponsorship of select investigator initiated trials (IITs) in HCC and colorectal cancer liver metastases (mCRC) and the establishment of a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe.

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 next twelve months, but anticipates that additional working capital will 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 clinical research, 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.

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, 2015 and 2014; 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 or any interim period.

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 the Company's Annual Report on Form 10-K filed for the period ended December 31, 2014. There were no newly adopted policies or significant change in existing policies that occurred during the quarter ended March 31, 2015.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers ("ASU 2014-09") that updates the principles for recognizing revenue. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also amends the required disclosures of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company expects to adopt this guidance when effective, and does not anticipate that this guidance will materially impact its consolidated financial statements.

In June 2014, the FASB issued ASU 2014-12, Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period ("ASU 2014-12"). ASU 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant-date fair value of the award. ASU 2014-12 is effective for annual reporting periods beginning after December 15, 2015, with early adoption permitted. The Company expects to adopt this guidance when effective, and does not anticipate that this guidance will materially impact its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements — Going Concern, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). ASU 2014-15 requires management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the ASU (1) provides a definition of the term substantial doubt, (2) requires an evaluation every reporting period including interim periods, (3) provides principles for considering the mitigating effect of management's plans, (4) requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) requires an express statement and other disclosures when substantial doubt is not alleviated, and (6) requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). This standard is effective for the fiscal years ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The Company is currently evaluating the accounting transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

(2) Inventories

Inventories consist of the following:

(in thousands)

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	March 31, 2015	December 31, 2014
Raw materials	\$ 166	\$ 203
Work-in-process	72	63