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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x 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

o 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.)

1301 Avenue of the Americas, 43FL

(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 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 o Accelerated filer o

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

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.

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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

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 cholangiocarncinoma (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)

	March 31, 2015	December 31, 2014
Raw materials	$ 166	$ 203
Work-in-process	72	63
Finished goods	36	83
Total inventory	$ 274	$ 349

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	March 31, 2015	December 31, 2014
Insurance premiums	$ 394	$ 591
Kits for clinical use	145	161
Taxes	143	5
Other	300	217
Total prepaid expenses and other current assets	$ 982	$ 974

(4) Property, Plant, and Equipment
Property, plant, and equipment consist of the following:

(in thousands)	March 31, 2015	December 31, 2014
Leaseholds	$1,633	$ 1,629
Enterprise hardware and software	1,569	1,573
Furniture	355	361
Equipment	1,387	1,380
Buildings and land	603	603
Property, plant and equipment, gross	5,547	5,546
Accumulated depreciation	(3,927)	(3,748)
Property, plant and equipment, net	$1,620	$ 1,798

Depreciation expense for both the three months ended March 31, 2015 and 2014 was approximately $0.2 million.

(5) Accrued Expenses
Accrued expenses consist of the following:

(in thousands)	March 31, 2015	December 31, 2014
Compensation, excluding taxes	$1,937	$ 2,187
Professional fees	249	341
Short-term portion of lease restructuring	209	239
Deferred rent	43	58
Other	697	778
Total accrued expenses	$3,135	$ 3,603

(6) Restructuring Expenses
Beginning in 2013, the Company has implemented several workforce restructurings to reduce operating costs, 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 59 employees. As a result of termination benefits provided to these employees the Company has incurred a total restructuring charge of approximately $5.5 million for employee related expenses. At March 31, 2015, the remaining restructuring reserve of approximately $0.9 million is included in Accrued expenses on the condensed consolidated balance sheets.

In order to help reduce operating costs and more appropriately align its office space with the reduced size of its workforce, the Company has entered into two sub-leases for office space at its 810 Seventh Avenue office. On May 22, 2014, the Company entered into a sub-lease agreement ("Sub-lease #1") for approximately one-half of the office space at this location ("Suite 3500"), resulting in a lease restructuring reserve of approximately $0.9 million. On August 18, 2014, the Company entered into a sub-lease agreement ("Sub-lease #2") with a third party for the remaining one-half of office space at its 810 Seventh Avenue office ("Suite 3505"), resulting in a lease restructuring reserve of approximately $0.7 million. As of March 31, 2015, the total remaining lease restructuring liability for its leased office space was approximately $1.2 million, of which approximately $0.2 million and $1.0 million were included in Accrued expenses and Other non-current liabilities on the condensed consolidated balance sheets, respectively.

The following table provides the year-to-date activity of the Company's restructuring reserves as of March 31, 2015:

(in thousands)	Employee Costs	Lease Liability
Reserve balance at December 31, 2014	$ 824	$ 1,282
Charges	403	—
Payments/Utilizations	(358)	(87)
Reserve balance at March 31, 2015	$ 869	$ 1,195

(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. 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 March 2013, the Company entered into an agreement with Cowen and Company LLC ("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 year ended December 31, 2014 the Company sold an additional 1.0 million shares of its common stock under this ATM program for proceeds of approximately $4.8 million, with net cash proceeds after related expenses of approximately $4.7 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, 2015, the Company has approximately $39.9 million remaining under the program subject to market conditions and certain limitations.

The Company currently has two active registration statements on Forms S-3. Form S-3 limits the aggregate market value of securities that Delcath is permitted to offer in any 12 month-period under Form S-3 to one-third of its public float. Given the Company's offering in February 2015, other sales under the market equity offering program during the relevant 12 month-period, and Delcath's current aggregate market value of securities, the Company is at the applicable limit under Form S-3. As a result, unless the market value of Delcath's securities increases the Company's ability to raise capital may be impaired and Delcath is currently unable to utilize the Form S-3 or access its at the market equity offering program.

Warrants

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 February 2015 sale of common stock and warrants. At March 31, 2015, the 2012 Warrants were

exercisable at $0.82 per share with approximately 260,000 warrants outstanding. The 2012 Warrants have a three-year term.

In October 2013, the Company completed the sale of 1.3 million shares of its common stock and the issuance of warrants to purchase approximately 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 became exercisable on April 30, 2014 and at March 31, 2015, the 2013 Warrants were exercisable at $7.04 per share with approximately 0.6 million warrants outstanding. The 2013 Warrants have a five-year term.

In February 2015, the Company completed the sale of 2.5 million shares of its common stock and the issuance of warrants to purchase 1.1 million common shares (the "2015 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $2.6 million, with net cash proceeds after related expenses from this transaction of $2.5 million. Of those proceeds, the Company allocated an estimated fair value of $0.8 million to the 2015 Warrants. At March 31, 2015, the 2015 Warrants were exercisable at $1.38 per share with approximately 1.1 million warrants outstanding. The 2015 Warrants have a five-year term.

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.

For the three months ended March 31, 2015, the Company recognized compensation expense of approximately $0.1 million relating to stock options granted to employees. For the three months ended March 31, 2014, the Company recognized compensation expense of approximately $0.2 million.

For the three months ended March 31, 2015, the Company recognized compensation expense of approximately $0.02 million related to restricted stock granted to employees. For the three months ended March 31, 2014, the Company recognized compensation expense of approximately $0.04 million.

There were no stock options or restricted stock awards granted during the three months ended March 31, 2015 or 2014.

(8) Fair Value Measurements
Derivative Warrant Liability

As disclosed in Note 7 Stockholders' Equity of these condensed consolidated financial statements, the Company allocated part of the proceeds of public offerings in 2012, 2013 and 2015 of the Company's common stock to warrants ("the Warrants") issued in connection with those transactions. The valuation of the warrants was determined using an option pricing model. This model uses inputs such as the underlying price of the shares issued at the measurement date, volatility, risk free interest rate and expected life of the instrument. The Company has classified the Warrants as a current liability due to the holders ability to exercise the warrants at any time before the expiration date and has accounted for them as derivative instruments in accordance with ASC 815, adjusting the fair value at the end of each reporting period. Additionally, the Company has determined that the warrant derivative liability should be classified

within Level 3 of the fair-value hierarchy by evaluating each input for the option pricing model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value classification as called for in ASC 820. There are six inputs: closing price of Delcath stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of Delcath's stock over that term; annual rate of dividends; and the riskless rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrant agreements. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of Delcath stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10). The riskless rate of return is a Level 2 input as defined in ASC 820-10, while the historical volatility is a Level 3 input as defined in ASC 820. Since the lowest level input is a Level 3, Delcath determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

For the three months ended March 31, 2015, the Company recorded pre-tax derivative warrant income of $0.2 million. The resulting derivative warrant liabilities totaled $0.8 million at March 31, 2015. In the event of a hypothetical 10% increase in the market price of our common shares on which the March 31, 2015 valuation was based, the value of the derivative liability would have increased by approximately $0.1 million. Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at March 31, 2015 was determined by using an option pricing model with the following assumptions:

	2015	2013	2012
	Warrants	Warrants	Warrants
Expected volatility	89.08%	90.64%	76.58%
Risk-free interest rates	1.31%	1.01%	0.03%
Expected life (in years)	4.88	3.58	0.17

Money Market Funds

The Company has determined that the inputs associated with the fair value determination of its money market funds are based on quoted prices (unadjusted) and, as a result, the investments have been classified within Level 1 of the fair value hierarchy.

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2015, aggregated by the level in the fair value hierarchy within which those measurements fall in accordance with ASC 820.

	Assets and Liabilities Measured at Fair Value on a Recurring Basis			
(in thousands)	Level 1	Level 2	Level 3	Balance at March 31, 2015
Assets				
Money market funds	$1,943	$ —	$—	$ 1,943
Liabilities				
Derivative instrument liabilities	$—	$ —	$836	$ 836

The table below presents the activity within Level 3 of the fair value hierarchy for the three months ended March 31, 2015:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at December 31, 2014	$ 225
Total change in the liability included in earnings	(209)
Fair value of warrants issued	820
Balance at March 31, 2015	$ 836

(9) Net Loss per Common Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as stock options and warrants calculated using the treasury stock method. In periods with reported net operating losses, all common stock options and warrants are generally deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which the exercise price of the warrants was less than the last reported sales price of Delcath's common stock on the final trading day of the period and there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, the impact of gains related to the mark-to-market adjustment of the warrants outstanding at the end of the period is reversed and the treasury stock method is used to determine diluted earnings per share.

For the three months ended March 31, 2015 and 2014, basic and diluted net loss per common share are equal.

The following potentially dilutive securities were excluded from the computation of earnings per share as of March 31, 2015 and 2014 because their effects would be anti-dilutive:

	March 31, 2015	2014
Stock options	274,229	237,829
Unvested restricted shares	28,934	18,663
Warrants	1,957,157	891,368
Total	2,260,320	1,147,860

(10) Taxes

As discussed in Note 13 Income Taxes of the Company's Annual Report, the Company has a valuation allowance against the full amount of its net deferred tax assets. The Company currently provides a valuation allowance against deferred tax assets when it is more likely than not that some portion or all of its deferred tax assets will not be realized. The Company has not recognized any unrecognized tax benefits in its balance sheet.

The Company is subject to income tax in the U.S., as well as various state and international jurisdictions. The Company has not been audited by the U.S. Internal Revenue Service, international tax authorities, or any states in connection with income taxes. The Company's New York State tax returns have been subject to annual desk reviews which have resulted in insignificant adjustments to the related franchise tax liabilities and credits. The Company's tax years generally remain open to examination for all federal, state and foreign tax matters until its net operating loss carryforwards are utilized and the applicable statutes of limitation have expired. The federal and state tax authorities can generally reduce a net operating loss (but not create taxable income) for a period outside the statute of limitations in order to determine the correct amount of net operating loss which may be allowed as a deduction against income for a period within the statute of limitations.

(11) Commitment and Contingencies

The Company is a party to several legal proceedings. Refer to Part II, Item 1 Legal Proceedings in this Quarterly Report on Form 10-Q for more information.

(12) Subsequent Events

The Company completed an evaluation of the impact of any subsequent events through the date financial statements were issued and determined there were no subsequent events requiring disclosure in or adjustment to these financial statements.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and notes thereto contained in Item 1 of Part I of this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2014 included in the Company's 2014 Annual Report on Form 10-K to provide an understanding of its results of operations, financial condition and cash flows.

Disclosure Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q for the period ended March 31, 2015 contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Quarterly Report on Form 10-Q for the period ending March 31, 2015 that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Quarterly Report on Form 10-Q for the period ended March 31, 2015 in Part II, Item 1A under "Risk Factors" as well as in Part I, Item 3 "Quantitative and Qualitative Disclosures About Market Risk," our Annual Report on Form 10-K for the period ended December 31, 2014 in Item 1A under "Risk Factors" as well as in Item 7A "Quantitative and Qualitative Disclosures About Market Risk," and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT/Melphalan/HDS, generate revenue and successfully obtain reimbursement for the procedure and System;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of the system and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT/Melphalan/HDS;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners; and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

Overview

The following section should be read in conjunction with Part I, Item 1: Condensed Consolidated Financial Statements of this report as well as Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's 2014 Annual Report on Form 10-K.

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 cholangiocarncinoma (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 direction and focus of our CDP for CHEMOSAT/Melphalan/HDS is informed by our prior clinical development program, which was conducted between 2004 and 2010. This prior program included a Phase 3 trial in 93 patients that demonstrated efficacy for Melphalan/HDS in ocular melanoma liver metastases, and a Phase 2 multi-histology trial in 56 patients that also provided an efficacy signal for Melphalan/HDS in HCC. Our CDP is also informed by non-clinical, commercial CHEMOSAT cases performed on over 100 patients in Europe, and prior regulatory experience with the FDA. Experience gained from this research, development, early European commercial and U.S. regulatory activity has led to the implementation of several safety improvements to both our product and the associated medical procedure.

In the United States, Melphalan/HDS is considered a combination drug and device product, and is regulated as a drug by the FDA. The FDA has granted us five orphan drug designations, including two orphan designations for the use of the drug melphalan for the treatment of patients with ocular melanoma liver metastases and HCC. Melphalan/HDS has not been approved for sale in the United States.

In Europe, the current version of our CHEMOSAT product is regulated as a Class IIb medical device and received its CE Mark in 2012. We are in an early phase of commercializing CHEMOSAT in select markets in the European Union (United Kingdom and Germany) where we believe the prospect of securing adequate reimbursement for the procedure is strongest.

Currently there are few effective treatment options for certain cancers in the liver. Traditional treatment options include surgery, chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. We believe that CHEMOSAT/Melphalan/HDS represents a potentially important advancement in regional therapy for primary liver cancer and certain other cancers metastatic to the liver. We believe that CHEMOSAT/Melphalan/HDS is uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies.

Cancers in the Liver – A Significant Unmet Need

Cancers of the liver remain a major unmet medical need globally. According to GLOBOCAN and American Cancer Society (ACS) Facts & Figures 2008, approximately 1.2 million patients globally are diagnosed each year with primary liver cancer or cancer that has metastasized to the liver. According to the American Cancer Society's (ACS) Cancer Facts & Figures 2013 report, cancer is the second leading cause of death in the United States, with an estimated 580,350 deaths and 1,660,290 new cases expected to be diagnosed in 2013. Cancer is one of the leading causes of death worldwide, accounting for approximately 8.2 million deaths and 14.1 million new cases in 2012 according to GLOBOCAN. The financial burden of cancer is enormous for patients, their families and society. The National Institutes of Health (NIH) estimates that the overall costs of cancer in 2008 were $201 billion: $77 billion for direct medical costs (total of all health expenditures) and $124 billion for indirect mortality costs (cost of lost productivity due to premature death). The liver is often the life-limiting organ for cancer patients and one of the leading causes of cancer death. Patient prognosis is generally poor once cancer has spread to the liver.

Liver Cancers—Incidence and Mortality

There are two types of liver cancers: primary liver cancer and metastatic liver disease. Primary liver cancer (hepatocellular carcinoma or HCC, including intrahepatic bile duct cancers or ICC) originates in the liver or biliary tissue and is particularly prevalent in populations where the primary risk factors for the disease, such as hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants, are present. Metastatic liver disease, also called liver metastasis, or secondary liver cancer, is characterized by microscopic cancer cell clusters that detach from the primary site of disease and travel via the blood stream and lymphatic system into the liver, where they grow into new tumors. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological functions of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize to their liver. In the United States, metastatic liver disease is more prevalent than primary liver cancer.

Ocular Melanoma

Ocular melanoma is one of the cancer histologies with a high likelihood of metastasizing to the liver. We estimate that up to 8,600 cases of ocular melanoma are diagnosed in the U.S. and Europe annually, and that approximately 55% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, we estimate that approximately 90% of patients will develop liver involvement. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally six to eight months. Currently there is no standard of care for patients with ocular melanoma liver metastases. As a result, we estimate that up to 4,300 patients with ocular melanoma liver metastases in the U.S. and Europe may be eligible for treatment with the Melphalan/HDS.

Hepatocellular Carcinoma (HCC) and Intrahepatic Cholangiocarcinoma (ICC)

Hepatobiliary cancers---including HCC and ICC---are among the most prevalent and lethal forms of cancer. According to GLOBOCAN, an estimated 76,000 new cases of primary liver cancers are diagnosed in the U.S. and Europe annually. Approximately 90% of these patients are diagnosed with HCC. Excluding patients who are eligible for surgical resection or certain focal treatments, we estimate that approximately 15,000 patients with HCC in the U.S. and Europe may be eligible for treatment with Melphalan/HDS. We estimate that an additional 6,500 patients diagnosed with ICC may also be eligible for treatment with Melphalan/HDS. According to the ACS, the overall five-year survival rate for liver cancer patients in the U.S is approximately 15% compared to 68% for all cancer combined. Globally, with 782,000 new cases in 2012, HCC was the fifth most common cancer in men and the ninth in women according to GLOBOCAN. GLOBOCAN estimates indicate that HCC was responsible for 746,000 deaths in 2012 (9.1% of the total cancer deaths), making it the second most common cause of death from cancer worldwide.

The prognosis for primary liver cancer is very poor, as indicated by an overall ratio of mortality to incidence of 0.95. The American Cancer Society’s Cancer Facts & Figures 2013 outlines the treatment options for HCC as follows: “Early stage HCC can sometimes be successfully treated with surgery in patients with sufficient healthy liver tissue; liver transplantation may also be an option. Surgical treatment of early stage HCC is often limited by pre-existing liver disease that has damaged the portion of the liver not affected by cancer. Patients whose tumors cannot be surgically removed may choose ablation (tumor destruction) or embolization, a procedure that cuts off blood flow to the tumor.

Fewer treatment options exist for patients diagnosed at an advanced stage of the disease. Sorafenib (Nexavar) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery."

About CHEMOSAT/Melphalan/HDS

CHEMOSAT/Melphalan/HDS administers concentrated regional chemotherapy to the liver. This "whole organ" therapy is performed by isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and then filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion (PHP), three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body's circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by our proprietary filters. The filters absorb chemotherapeutic agent in the blood, thereby reducing systemic exposure to the drug and related toxic side effects, before the filtered blood is returned to the patient's circulatory system.

The PHP procedure is performed in an interventional radiology suite in approximately two to three hours. Patients remain in an intensive care or step-down unit overnight for observation following the procedure. Treatment with CHEMOSAT/Melphalan/HDS is repeatable, and a new disposable CHEMOSAT/Melphalan/HDS is used for each treatment. In early clinical trials patients received an average of three procedures in four to eight week intervals. Patients treated in both clinical and non-clinical settings have received up to six treatments. In the United States, melphalan hydrochloride for injection will be included with the system. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party.

Prior Clinical Development

Our Phase 3 clinical trial and multi-arm Phase 2 clinical trial of the Melphalan/HDS with melphalan in patients with liver cancers are summarized below. The Phase 3 and Phase 2 clinical trials were subject to the terms and conditions of the Cooperative Research and Development Agreement (CRADA), between the Company and the National Cancer Institute (NCI). The Phase 3 trial was conducted under an FDA Special Protocol Assessment (SPA) and was conducted at centers throughout the United States.

Phase 3—Melanoma Metastases Trial

The most advanced application for which Melphalan/HDS was evaluated is for the treatment of metastatic melanoma in the liver. In February 2010, we concluded a randomized Phase 3 multi-center study for patients with unresectable metastatic ocular or cutaneous melanoma exclusively or predominantly in the liver. In the trial, patients were randomly assigned to receive PHP treatments with melphalan using the Melphalan/HDS, or to a control group providing best alternative care (BAC). Patients assigned to the PHP arm were eligible to receive up to six cycles of treatment at approximately four to eight week intervals. Patients randomized to the BAC arm were permitted to cross-over into the PHP arm at radiographic documentation of hepatic disease progression. A majority of the BAC patients did in fact cross over to the PHP arm. Secondary objectives of the study were to determine the response rate, safety, tolerability and overall survival.

On April 21, 2010, we announced that our randomized Phase 3 clinical trial of PHP with melphalan using Melphalan/HDS for patients with unresectable metastatic ocular and cutaneous melanoma in the liver had successfully achieved the study's primary endpoint of extended hepatic progression-free survival, or hPFS. An updated summary of the results was presented at the European Multidisciplinary Cancer Congress organized by the European Cancer Organization (ECCO) and the European Society of Medical Oncology (ESMO) in September 2011. Data submitted in October 2012 to the FDA in Delcath's New Drug Application (NDA) comparing treatment with the PHP with melphalan (the treatment group) to BAC (the control group), showed that patients in the PHP arm had a statistically significant longer median hPFS of 7.0 months compared to 1.7 months in the BAC control group, according to the Independent Review Committee (IRC) assessment. This reflects a 4-fold increase of hPFS over that of the BAC arm, with 50% reduction in the risk of progression and/or death in the PHP treatment arm compared to the BAC control arm. Authors of this study submitted these results for publication in a leading peer-reviewed journal in February 2015.

Phase 2 Multi-Histology, Unresectable Hepatic Tumor Trial

Also in 2010, we concluded a separate multi-arm Phase 2 clinical trial of PHP with melphalan using an early version of the Melphalan/HDS in patients with primary and metastatic liver cancers, stratified into four arms: neuroendocrine tumors (carcinoid and pancreatic islet cell tumors), ocular or cutaneous melanoma, metastatic colorectal adenocarcinoma (mCRC), and HCC. In the metastatic neuroendocrine (mNET) cohort (n=24), the objective tumor response rate was 42%, with 66% of patients achieving hepatic tumor shrinkage and durable disease stabilization. In the mCRC cohort, there was inconclusive efficacy possibly due to advanced disease status of the patients. Similar safety profiles were seen across all tumor types studied in the trial.

Phase 2 Multi-Histology Clinical Trial - HCC Cohort

In the HCC cohort (n=8) of our Phase 2 Multi-Histology trial, a positive signal in hepatic malignancies was observed in 5 patients. Among these patients, one patient received four treatments, achieved a partial response lasting 12.22 months, and survived 20.47 months. Three other patients with stable disease received 3-4 treatments, with hepatic progression free survival (hPFS) ranging 3.45 to 8.15 months, and overall survival (OS) ranging 5.26 to 19.88 months. There was no evidence of extrahepatic disease progression. The observed duration of hPFS and OS in this limited number of patients exceeded that generally associated with this patient population. We believe these results constitute a promising signal that warrants further clinical investigation.

Risks associated with the CHEMOSAT/Melphalan/HDS Procedure

As with many cancer therapies, treatment with CHEMOSAT/Melphalan/HDS is associated with toxic side effects and certain risks, some of which are potentially life threatening. In our Phase 2 and 3 clinical trials using early versions of CHEMOSAT/Melphalan/HDS and treatment protocol, the integrated safety population of patients treated with CHEMOSAT/Melphalan/HDS showed these risks to include: a 4.1% incidence of deaths due to adverse reactions; 4% incidence of stroke; 2% incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment; a ≥ 70% incidence of grade 4 bone marrow suppression with a median time of recovery of greater than 1 week; and 8% incidence of febrile neutropenia, along with the additive risk of hepatic injury, severe hemorrhage, and gastrointestinal perforation. In this integrated safety population, deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments.

Procedure and Product Refinements

The trials that comprised this integrated safety population used early versions of the device and procedure. As a consequence of these identified risks and experience gained in non-clinical, commercial usage in Europe, we have continued to develop and refine both the CHEMOSAT/Melphalan/HDS and the PHP procedure. The procedure refinements have included modifications to the pre-, peri- and post-procedure patient management and monitoring, as well as the use of the following: prophylactic administration of proton pump inhibitors, prophylactic platelet transfusions, prophylactic hydration at key pre-treatment intervals, use of vasopressor agents coupled with continuous monitoring for maintenance of blood pressure and prophylactic administration of growth factors to reduce risk of serious myelosuppression. In addition, in 2012, we introduced the Generation Two version of the CHEMOSAT system, which offered improved hemofiltration and other product enhancements.

Reports from treating physicians in both Europe and the U.S. using the Generation Two CHEMOSAT/Melphalan/HDS in a non-clinical, commercial setting have suggested that these product improvements and procedure refinements have improved the safety profile.

Clinical Development Program

The focus of our CDP is to generate clinical data for the CHEMOSAT/Melphalan/HDS in various disease states and validate the safety profile of the current version of the product and treatment procedure. The program also seeks to address the requirements contained in the FDA's Complete Response Letter (CRL) received in September 2013, which was issued in response to our New Drug Application, which we submitted in 2012 seeking an indication in ocular melanoma liver metastases. We believe that the improvements we have made to CHEMOSAT/Melphalan/HDS and to the PHP procedure have addressed the severe toxicity and procedure-related risks observed during the previous Phase 2 and 3 clinical trials. The CDP is also designed to support clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support regulatory approvals in various jurisdictions, including the U.S.

Global Phase 3 Ocular Melanoma Trial

Ocular melanoma is one of the cancer histologies with a high likelihood of metastasizing to the liver. Once ocular melanoma has spread to the liver, current evidence suggests median overall survival for these patients is generally six to eight months. According to the ACS and other international health agencies, approximately 8,600 cases of ocular melanoma are diagnosed annually in the U.S. and Europe. Over half of these patients will develop metastatic disease and approximately 90% of these patients will have liver involvement. As a result, we believe that up to 4,300 patients eligible for treatment with the CHEMOSAT/Melphalan/HDS. There currently is no standard of care for the treatment of ocular melanoma metastatic to the liver. Melphalan Hydrochloride has been granted orphan drug status by FDA for treatment of patients with ocular melanoma.

We are advancing plans to initiate a pivotal Phase 3 overall survival (OS) clinical trial in ocular melanoma that is metastatic to the liver for resubmission of our NDA to the FDA. Based on the strength of the efficacy data in this disease observed in our previous Phase 3 clinical trial and the reports of an improved safety profile from over 100 patients treated in a non-clinical trial setting in Europe, we are confident that this program can address the concerns raised by the FDA in its CRL. We are working with the relevant Health Authorities in Europe and the U.S. to initiate this trial. We believe that ocular melanoma liver metastases represent a high unmet medical need, and that pursuit of an indication in this disease state may be the fastest path to potential approval of the Melphalan/HDS in the U.S.

Phase 2 Hepatocellular Carcinoma (HCC) & Intrahepatic Cholangiocarcinoma (ICC) Program

We have initiated a new clinical trial program in Europe and the U.S., with the goal of obtaining an efficacy and safety signal for Melphalan/HDS in the treatment of HCC and ICC. Due to differences in treatment practice patterns between Europe and the U.S., we established separate European and U.S. trial protocols for the HCC Phase 2 program with different inclusion and exclusion patient selection criteria:

- Protocol 201 – Conducted in the U.S., this trial will assess the safety and efficacy of Melphalan/HDS followed by sorafenib. The trial will evaluate overall response rate via modified Response Evaluation Criteria in Solid Tumors (mRECIST), progression free survival, characterize the systemic exposure of melphalan and assess patient quality of life. The Moffitt Cancer Center opened for enrollment in this trial October 2014, and Montefiore Medical Center in April 2015.

- Protocol 202 – conducted in Europe, this trial will assess the safety and efficacy of Melphalan/HDS without sorafenib. The trial will also evaluate overall response rate via (mRECIST) criteria, progression free survival, characterize the systemic exposure of melphalan and assess patient quality of life. Three hospitals in Germany have opened for enrollment --- Goethe University Hospital, Hannover Medical School Hospital and Jena University Hospital. We intend to open additional centers in Germany and the U.K., subject to the applicable authorizations and approvals including ethics committee approval at participating hospitals.
- ICC Cohort – In 2015 we expect to expand Protocol 202 to include a cohort of patients with ICC. We expect the trial for this cohort will be conducted at the same centers participating in the Phase 2 HCC trial.

Clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator treatment or required prior therapy.

European Investigator Initiated Trials

In addition to the clinical trials in our CDP, we are supporting data generation in other areas. We are currently supporting two Investigator Initiated Trials (IITs) in Europe– one in colorectal carcinoma metastatic to the liver (mCRC) at Leiden University Medical Center in The Netherlands, and another in HCC at Goethe University Hospital in Frankfurt Germany. Both of these trials have opened for enrollment. We continue to evaluate other IITs as suitable opportunities present in Europe. We believe IITs will serve to build clinical experience at key cancer centers, and will help support efforts to obtain full reimbursement in Europe.

European Clinical Data Generation

On April 2, 2015 we announced the activation of our prospective patient registry in Europe to collect uniform essential patient safety, efficacy, and Quality of Life (QoL) information using observational study methods. This registry will gather data in multiple tumor types from commercial cases performed by participating cancer centers in Europe. A prospective registry is an organized system that uses observational study methods to collect defined clinical data under normal conditions of use to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure. Registry data is non-randomized, and as such cannot be used for either registration approval, promotional or competitive claims. However, we believe the Patient Registry will provide a valuable data repository from a commercial setting that can be used to support clinical adoption and reimbursement in Europe.

Recent Data Presentation

In March 2015, results from a single-center retrospective study were presented in at the Society of Surgical Oncology (SSO) Annual Meeting. In a poster presented by Andrea Abbott, M.D., Surgical Oncology, Moffitt Cancer Center entitled Hepatic Progression Free and Overall Survival after Regional Therapy to the Liver for Metastatic Melanoma, investigators evaluated outcomes from 30 patients with cutaneous or uveal melanoma that metastasized to the liver following treatment with yttrium-90 (Y90), chemoembolization (CE) or percutaneous hepatic perfusion (PHP) with

Melphalan/HDS. Outcomes on hepatic progression free survival (HPFS), progression free survival (PFS) and overall survival (OS) were compared. In the study six patients received Y90, 10 patients were treated with PHP, 12 patients were treated with CE, one patient received Y90 after PHP and one patient received PHP following treatment with CE. Kaplan-Meier survival estimates, log-rank tests and multivariate time-dependent Cox regression analyses (MVA) were used to relate patient, tumor and treatment variables to HPFS, PFS and OS. The study showed a significant difference in median HPFS with 54 days for patients treated with Y90, 80 days for patients treated with CE and 310 days for those treated with PHP (p=0.002). MVA showed improved HPFS for PHP versus Y90 (p=0.001) and for PHP versus CE (p=0.008), but not for CE versus Y90 (p=0.44). Median OS from time of treatment was longest for PHP at 736 days versus Y90 285 days and CE 265 days; however it did not reach statistical significance. There was a significant difference on MVA of OS for PHP versus Y90 (p = 0.03) but not for PHP versus CE (p=0.37) or CE versus Y90 (0.06).

A link to this study is available on the SSO website.

Market Access & Commercial Clinical Adoption

European Union

With continued economic and reimbursement challenges in certain European markets, our immediate market access and clinical adoptions efforts continue to be focused on the key target markets of Germany and the United Kingdom, which represent a majority of the total potential liver cancer market (primary and metastatic) in the EU and where progress in securing reimbursement for CHEMOSAT treatments offers the best near-term opportunities. We also continue to support clinical adoption of CHEMOSAT in the Netherlands, Spain, France and Italy. We employ a combination of direct and indirect sales channels to market and sell CHEMOSAT in these markets. Our European Headquarters is in Galway, Ireland.

Since its February 2012 launch, CHEMOSAT has been used to perform 182 treatments. During the first quarter of 2015, 26 CHEMOSAT commercial treatments were performed, with 16 of these representing retreatments.

Since launching CHEMOSAT in Europe, treatments have been performed at 20 leading European cancer centers. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver primarily ocular melanoma liver metastases, and other tumor types, including hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, and cutaneous melanoma.

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of reimbursement mechanisms for the procedure in our priority markets. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis. Medical devices are typically reimbursed under Diagnosis Related Groups (DRG) as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, the Company is actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. In most EU countries, the government provides healthcare and controls reimbursement levels. Since the EU has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country.

Germany

In February 2015, we announced that the Institut f r das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, again granted Value 4 coverage status for the treatment of patients with liver metastases with CHEMOSAT. The InEk determines three status levels for medical procedures submitted for its review: Value 1 (mandated reimbursement), Value 2 (declined for reimbursement), and Value 4 (negotiated reimbursement). The InEk may also decline to make a determination regarding an application. Under the Neue Untersuchungs und Behandlungsmethoden (NUB) reimbursement scheme, Value 4 Status, while not mandating reimbursement, allows participating cancer centers to negotiate a budget to fund reimbursement coverage for CHEMOSAT procedure with

insurers serving their region. The InEk first established NUB Value 4 status for CHEMOSAT procedures in 2013, and repeated this assessment in 2014. The NUB is an annual process, and participating centers in Germany are required to apply each year for subsequent coverage under the NUB scheme.

Separately, throughout 2014 physicians and patients in Germany submitted and received approvals for Individual Funding Requests (IFRs) granting reimbursement for the treatment of liver metastases with CHEMOSAT. IFRs are case-by-case appeals for reimbursement made to the patient's insurance carrier ("sickness funds"). While each IFR is evaluated independently, the majority of these applications were approved during the year. Of those IFRs that were initially rejected, subsequent appeals over-ruled most of these rejections and allowed treatments to be funded. IFR approvals have covered a range of sickness funds across a number of regions in Germany including ocular melanoma, cutaneous melanoma, intrahepatic cholangiocarcinoma, colorectal carcinoma, pancreatic cancer and sarcoma; and some were granted for multiple treatments of the same patients. We expect that IFRs will continue to be the main reimbursement vehicle in the German market in 2015.

The German Radiology Society resubmitted its application for ZE (Zusatzentgeld) for CHEMOSAT in March 2015, but did not affect the relevant DRG codes in 2014. ZE is a national interim reimbursement code granted by the InEk until a specific DRG code can be created. A ZE code is dependent on having enough financial data related to the procedure to establish cost averages, and our efforts are focused on ensuring that treatment and cost data from specific hospitals are provided to the InEk to support a future ZE application.

United Kingdom

In the United Kingdom, though Delcath and our participating cancer centers identified existing Healthcare Resource Groups (HRG) code(s), we have been advised that hospitals have not used it for coverage of CHEMOSAT related costs. We continue to work with the HRG organization that decides on new HRG codes toward receipt of a dedicated and permanent reimbursement code in the future.

Throughout 2014, we supported efforts to seek a block fund grant through the Commissioning Through Evaluation (CTE) process, which may ultimately provide funding for up to 50-75 ocular melanoma patients to be treated utilizing CHEMOSAT at two or three centers in the U.K. This process has been driven by our partner centers and their clinical community, with the centers applying for funding for a limited number of patients with ocular melanoma. In the fourth quarter of 2014, Aintree University Hospital in Liverpool was activated with the intention of it becoming one of these CTE centers. The British healthcare system continues to evolve however, and ongoing changes to the CTE process and funding streams have resulted in delays that made the award and timing of any block grant funding difficult to predict. The entire CTE funding mechanism is a new process and the ongoing policy changes in the National Health Service (NHS) make it difficult to predict the likelihood of success in the near term.

In May 2014, the National Institute for Clinical Excellence (NICE), a non-departmental public body that provides guidance and advice to improve health and social care in the UK, completed a clinical review of CHEMOSAT. The NICE review indicated that as the current body of evidence on the safety and efficacy of PHP with CHEMOSAT for primary or metastatic liver cancer is limited, the procedure should be performed within the context of research by clinicians with specific training in its use and techniques. NICE stated that this research may take the form of observational studies. With UK participation in our Phase 2 HCC and ICC trial expected to begin in 2015, we believe the data generated from these studies will help provide supporting clinical data and address the concerns raised by NICE relative to survival, quality of life and adverse events. NICE may decide to conduct a Technology Appraisal of CHEMOSAT thereafter, the outcome of which could influence the long-term reimbursement status.

Public patients will continue to be treated in the UK through clinical trials and potentially the CTE process. Private patients will continue to be treated through the established private treatment pathway such as private insurance coverage or self-pay.

Other European Markets

Permanent reimbursement coverage in remaining EU markets will require additional time to secure. In the interim period, we are seeking payment through various avenues, including new technology programs. In France, we plan to present our Phase 3 trial data to the French healthcare authorities assuming publication in 2015 to set the foundation for a potential DRG code in 2016.

For France, Spain and the Netherlands, publication of the Phase 3 trial manuscript is a key component of the reimbursement process. The Phase 3 trial manuscript has been submitted and we expect publication in 2015.

Distribution Partners

As a result of the Company's strategy to prioritize resources on the key direct markets of Germany and the United Kingdom, the Company expects that its distribution strategy will continue to play a lesser role in its current commercial activities. In Spain, the Company has determined that there was no benefit to continuing with an indirect model and therefore terminated its relationship with its distributor in Spain and is now represented in Spain through a sales agency.

Regulatory Status

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in Warning Letters, fines, civil or criminal penalties, suspension or delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

U.S. Regulatory History

In August 2012, we submitted our New Drug Application (NDA) for the Melblez Kit under Section 505(b)(2) of the Federal Food Drug Cosmetic Act (FFDCA) seeking an indication for the percutaneous intra-arterial administration of melphalan for use in the treatment of patients with metastatic melanoma in the liver, and subsequently amended the indication to ocular melanoma metastatic to the liver. Our NDA was accepted for filing by the Food and Drug Administration (FDA) on October 15, 2012, and was designated

for standard review with an initial Prescription Drug User Fee Act (PDUFA) goal date of June 15, 2013. On April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013. On May 2, 2013 the Company announced that an Oncologic Drug Advisory Committee (ODAC) panel convened by the FDA voted 16 to 0, with no abstentions, that the benefits of treatment with the Melblez Kit do not outweigh the risks associated with the procedure using the early clinical trial versions of the system. Data submitted to the FDA used the early clinical trial versions of the system along with early clinical procedure techniques.

Complete Response Letter

On September 12, 2013, the FDA issued a complete response letter (CRL) regarding our NDA for Melblez Kit. The FDA issues a CRL after the review of a file has been completed and questions remain that preclude approval of the NDA in its current form. The FDA comments included, but were not limited to, a statement that Delcath must perform another "well-controlled randomized trial(s) to establish the safety and efficacy of Melblez Kit using overall survival as the primary efficacy outcome measure," and which "demonstrates that the clinical benefits of Melblez Kit outweigh its risks." The FDA also requires that the additional clinical trial(s) be conducted using the product the Company intends to market. In November 2013 Delcath and FDA participated in a meeting to discuss and clarify certain clinical, clinical pharmacology, Human Factors and product quality components of the CRL. We are working to incorporate the requirements referenced in the CRL into our clinical development program.

In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act (FFDCA), and it’s implementing regulations. The Delcath Melphalan/HDS is subject to regulation as a combination product, which means it is composed of both a drug product and device product. If marketed individually, each component would therefore be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of the Melphalan/HDS, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research (CDER), has primary jurisdiction over its pre-market development and review.

The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin and must be updated annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA’s Good Laboratory Practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

Orphan Drug Exclusivity

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting.

The FDA has granted Delcath five orphan drug designations. In November 2008, the FDA granted Delcath two orphan drug designations for the drug melphalan for the treatment of patients with cutaneous melanoma as well as patients with ocular melanoma. In May 2009, the FDA granted Delcath an additional orphan drug designation of the drug melphalan for the treatment of patients with neuroendocrine tumors. In August 2009, the FDA granted Delcath an orphan drug designation of the drug doxorubicin for the treatment of patients with primary liver cancer. In October 2013, the FDA granted Delcath orphan drug designation of the drug melphalan for the treatment of HCC.

The granting of orphan drug designations does not mean that the FDA has approved a new drug. Companies must still pursue the rigorous development and approval process that requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted at all or on a timely basis.

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could cause us or our third-party manufacturers to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP

regulations and other ongoing FDA regulatory requirements. If we or our present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require us to recall our products from distribution or withdraw any potential approvals of an NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, Warning Letters, corrective advertising and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

European Regulatory Environment

In the EEA, the CHEMOSAT system is subject to regulation as a medical device. The EEA is composed of the 28 Member States of the European Union plus Norway, Iceland, Liechtenstein, Switzerland and Turkey. Under the EU Medical Devices Directive (Directive No 93/42/ECC of 14 June 1993, as last amended), drug delivery products such as the CHEMOSAT system is governed by the EU laws on pharmaceutical products only if they are (i) placed on the market in such a way that the device and the pharmaceutical product form a single integral unit which is intended exclusively for use in the given combination, and (ii) the product is not reusable. In such cases, the drug delivery product is governed by the EU Code on Medicinal Products for Human Use (Directive 2001/83/EC, as last amended), while the essential requirements of the EU Medical Devices Directive apply to the safety and performance-related device features of the product. Because we do not intend to place the CHEMOSAT system on the EEA market as a single integral unit with melphalan, the product is governed solely by the EU Medical Devices Directive, while the separately marketed drug is governed by the EU Code relating to Medicinal Products for Human Use and other EU legislation applicable to drugs for human use.

CHEMOSAT is regulated as a Class IIb medical device. As a Class IIb medical device, the Notified Body is not required to carry out an examination of the product's design dossier as part of its conformity assessment prior to commercialization. The Company must continue to comply with the essential requirements of the EU Medical Devices Directive (Directive 93/42 EC) and is subject to a conformity assessment procedure requiring the intervention of a Notified Body. The conformity assessment procedure for Class IIb medical devices requires the manufacturer to apply for the assessment of its quality system for the design, manufacture and inspection of its medical devices by a Notified Body. The Notified Body will audit the system to determine whether it conforms to the provisions of the Medical Devices Directive. If the Notified Body's assessment is favorable it will issue a Full Quality Assurance Certificate, which enables the manufacturer to draw a Declaration of Conformity and affix the CE mark to the medical devices covered by the assessment. Thereafter, the Notified Body will carry out periodic audits to ensure that the approved quality system is applied by the manufacturer. In April 2012, we obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT system, and since this time all procedures in Europe have been performed with this version of the system.

A manufacturer without a registered place of business in a Member State of the European Union which places a medical device on the market under its own name must designate an authorized representative established in the European Union who can act before, and be addressed by, the Competent Authorities on the manufacturer's behalf with regard to the manufacturer's obligations under the EU Medical Devices Directive. We appointed such a representative prior to establishing our infrastructure in the EEA and expect that we will not need a third party representative in the future.

In the EEA, we must also comply with the Medical Device Vigilance System, which is designed to improve the protection of health and safety of patients, users and others by reducing the likelihood of recurrence of incidents related to the use of a medical device. Under this system, incidents are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. When a medical device is suspected to be a contributory cause of an incident, its manufacturer or authorized representative in the European Union must report it to the Competent

Authority of the Member State where the incident occurred. Incidents are generally investigated by the manufacturer. The manufacturer's investigation is monitored by the Competent Authority, which may intervene, or initiate an independent investigation if considered appropriate. An investigation may conclude in the adoption of a Field Safety Corrective Action (FSCA). An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification exchange and destruction. FSCAs must be notified by the manufacturer or its authorized representative to its customers and/or the end users of the medical device via a Field Safety Notice.

In the EEA, the off-label promotion of a pharmaceutical product is strictly prohibited under the EU Community Code on Medicinal Products, which provides that all information provided within the context of the promotion of a drug must comply with the information contained in its approved summary of product characteristics. Our product instructions and indication reference the chemotherapeutic agent melphalan hydrochloride. However, no melphalan labels in the EEA reference our product, and the labels vary from country to country with respect to the approved indication of the drug and its mode of administration. In the exercise of their professional judgment in the practice of medicine, physicians are generally allowed, under certain conditions, to use or prescribe a product in ways not approved by regulatory authorities. Physicians intending to use our device must obtain melphalan separately for use with the CHEMOSAT system and must use melphalan independently at their discretion.

In the EEA, the advertising and promotion of our products is also subject to EEA Member States laws implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Under the regulatory scheme in the EEA, we have received authorization to affix the CE Mark to CHEMOSAT as a device only, and physicians must separately obtain melphalan for use with CHEMOSAT. Our ability to market and promote CHEMOSAT is limited to this approved indication. Melphalan Hydrochloride for Injection is currently approved in 14 member states of the EEA, including the seven markets where procedures have been performed.

Other International Regulations

The CHEMOSAT device has received registrations in the following countries: Australia, New Zealand, Argentina, Taiwan, and Singapore. With limited resources and our attention focused on European commercial and clinical adoption efforts, pursuing other markets at this time is not practical. We will continue to evaluate commercial opportunities in these and other markets when resources are available and at an appropriate time.

Board of Directors Transition

In December 2014, we announced the appointment of Dr. Dennis H. Langer, William D. Rueckert and Dr. Marco Taglietti to the Company's Board of Directors. Dr. Langer will serve as a Class III director with his term expiring at the 2015 annual meeting; and Mr. Rueckert and Dr. Taglietti will both serve as Class I directors with terms expiring at the 2016 annual meeting. Concurrent with these additions, the Company also announced the resignations from the Board of Laura A. Brege, Tasos G. Konidaris, and Gabriel Leung. All such appointments and resignations were effective as of December 11, 2014.

Results of Operations for the Three Months Ended March 31, 2015; Comparisons of Results of Operations for the Three Months Ended March 31, 2014

Revenue

The Company recorded approximately $0.4 million in revenue related to product sales during the three months ended March 31, 2015. The Company recorded approximately $0.3 million in revenue during the same period of 2014.

Cost of Goods Sold

During the three months ended March 31, 2015, the Company recorded cost of goods sold of approximately $0.1 million. During the same period in 2014, the Company recorded cost of goods sold of approximately $0.1 million. As Delcath continues progress with clinical adoption, the Company expects to see a certain amount of volatility in both the average selling price and gross margin for the next several years. This volatility will be related to several factors, including: adjustments to volume forecasts; the expected use of third party distributors whose purchase prices will be lower than direct-to-customer prices; the gradual increase in cost of goods sold as the Company exhausts raw

materials that were purchased and expensed in prior periods and begins to recognize the actual costs of materials, labor and overhead; and an improvement in efficiencies as the Company increases its production of CHEMOSAT.

Selling, General and Administrative Expenses

For the three month periods ended March 31, 2015 and 2014, selling, general and administrative expenses were $3.0 million and $3.8 million, respectively. Included in these amounts are workforce restructuring charges of $0.4 million in 2015. Excluding these restructuring charges, selling, general and administrative expenses were $2.6 million for the three months ended March 31, 2015 compared to $3.8 million for the three months ended March 31, 2014, a decrease of $1.2 million. This decrease is primarily attributable to the Company's successful efforts to increase organizational efficiencies through lease and workforce restructurings as discussed in Note 6 to the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q, as well as the completion of its evaluation of potential strategic options during the leadership transition period..

Research and Development Expenses

For the three month periods ended March 31, 2015 and 2014, research and development expenses were $1.0 million and $1.5 million, respectively. This decrease is related to the phasing out of the Company's medical science liaison program during 2014 and the Company's successful efforts to increase organizational efficiencies through workforce restructurings discussed in Note 6 to the Company's interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

Interest Income

Interest income is from a money market account and interest earned on operating accounts. For the three months periods ended March 31, 2015 and 2014, the Company had interest income of approximately $1,605 and $1,357, respectively.

Other Expense and Interest Expense

Other expense is primarily related to foreign currency exchange gains and losses. Interest expense is related to an ongoing Revolving Line Facility Fee as required by the Loan and Security Agreement signed with Silicon Valley Bank in 2012 and discussed in Note 11 to the Company's audited financial statements contained in the 2014 Annual Report on Form 10-K.

Net Loss

The Company recorded a net loss for the three months ended March 31, 2015, of $3.5 million, a decrease of $1.8 million, or 33.9%, compared to a net loss of $5.3 million for the same period in 2014. This decrease in net loss is primarily due to a $1.3 million reduction in operating expenses, a $0.1 million improvement in gross profit, and a $0.4 million favorable change in the fair value of the warrant liability, a non-cash item. As detailed above, the Company has reduced operating costs through workforce restructurings that began in 2013, lease restructurings in 2014, and phased out its medical science liaison program in 2014.

Liquidity and Capital Resources

The Company's future results are subject to substantial risks and uncertainties. Delcath has operated at a loss for its entire history and anticipates that losses will continue over the coming years. There can be no assurance that Delcath will ever generate significant revenues or achieve profitability. The Company expects to use cash, cash equivalents and investment proceeds to fund its clinical and operating activities. Delcath's future liquidity and capital requirements will depend on numerous factors, including the initiation and progress of clinical trials and research and product development programs, obtaining approvals and complying with regulations; the timing and effectiveness of product commercialization activities, including marketing arrangements; the timing and costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; and the effect of competing technological and market developments.

At March 31, 2015, the Company had cash and cash equivalents totaling $18.5 million, as compared to cash and cash equivalents totaling $20.5 million and $31.3 million at December 31, 2014 and March 31, 2014, respectively. During the three months ended March 31, 2015 the Company used $4.4 million of cash in its operating activities, which compares to $4.5 million used for operating activities during the comparable period in 2014. The decrease of $0.1 million is primarily driven by improved efficiency in organization and operations. The Company believes that its capital resources are adequate to fund its operating activities into the first half of 2016.

Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to raise additional capital in order to fund its clinical development program or to fully commercialize the product. The Company continues to believe it will be able to raise additional capital in the event it is in its best interest to do so. The Company anticipates raising such additional capital by either borrowing money, selling shares of Delcath's capital

stock, or entering into strategic alliances with appropriate partners. 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 our business. Further, the Company's assumptions relating to its cash requirements may differ materially from its actual requirements because of a number of factors, including significant unforeseen delays in the regulatory approval process, changes in the focus and direction of clinical trials, lower revenue and increased costs related to commercializing the product.

The Company has funded its operations through a combination of private placements of its securities, public offerings in 2000, 2003, 2009, 2010, 2011, 2012, 2013 and 2015 registered direct offerings in 2007 and 2009, an "at the market" equity offering program initiated in 2012, and a committed equity financing facility program initiated in 2012. For a detailed discussion of the Company's various sales of securities and the "at the market" equity offering program see Note 7 to the Company's interim unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q.

On March 13, 2013, the Company filed a registration statement on Form S-3 with the SEC and also entered into a new sales agreement (the "March 2013 Sales Agreement") with Cowen and Company, LLC to sell shares of the Company's common stock, par value $.01 per share, having aggregate sales proceeds of $50.0 million, from time to time, through an "at the market" equity offering program under which Cowen and Company, LLC will act as sales agent. The registration statement became effective on May 1, 2013 (333-187230). As of March 31, 2015, Delcath had approximately $39.9 million available under this registration statement and intends to use this for its "at the market" equity offering program.

In December 2011, the Company filed a registration statement on Form S-3 with the SEC, which allowed the Company to offer and sell, from time to time in one or more offerings, up to $100 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deemed prudent or necessary to raise capital at a later date. The registration statement became effective on February 13, 2012. The Company used this registration statement for its May 2012 public offering detailed in Note 10 to the Company's audited financial statements contained in the 2013 Annual Report on Form 10-K. The Company subsequently filed a new shelf registration statement on Form S-3 (333-183675) with the SEC which became effective on October 9, 2012. This new shelf replaces the shelf registration filed in December 2011 and allows the Company to offer and sell, from time to time in one or more offerings, up to $100 million of common stock, preferred stock, warrants, debt securities and stock purchase contracts as it deems prudent or necessary to raise capital at a later date. The Company used this registration statement for its Common Stock Purchase Agreement with Terrapin Opportunity, L.P. detailed in Note 10 to the Company's audited financial statements contained in the 2013 Annual Report on Form 10-K. As of March 31, 2015, Delcath had approximately $77.6 million available under this registration statement, of which approximately $5.9 million is reserved for the potential issuance of shares upon the exercise of warrants.

Form S-3 limits the aggregate market value of securities that we are permitted to offer in any 12 month-period under Form S-3 to one-third of our public float. Given the offering in February 2015, other sales under our at the market equity offering program during the relevant 12 month-period, and our current aggregate market value of securities, we are at the applicable limit under Form S-3. As a result, unless the market value of our securities increases our ability to raise capital may be impaired and we currently are unable to utilize the Form S-3 or access our at the market equity offering program.

The Company intends to use the net proceeds from any future offerings for general corporate purposes, including, but not limited to, funding of clinical trials, obtaining regulatory approvals, commercialization of its products, capital expenditures and working capital.

Application of Critical Accounting Policies

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). Certain accounting policies have a significant impact on amounts reported in the financial statements. A summary of those significant accounting policies can be found in Note 3 to the Company's audited financial statements contained in the 2014 Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The Company may be minimally exposed to market risk through changes in market interest rates that could affect the interest earned on its cash balances.

The Company measures all derivatives, including certain derivatives embedded in contracts, at fair value and recognizes them on the balance sheet as an asset or a liability, depending on the Company's rights and obligations under the applicable derivative contract.

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 February 2015 sale of common stock and warrants. At March 31, 2015, the 2012 Warrants were exercisable at $0.82 per share with approximately 260,000 warrants outstanding. The 2012 Warrants have a three-year term.

In October 2013, the Company completed the sale of 1.3 million shares of its common stock and the issuance of warrants to purchase approximately 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 became exercisable on April 30, 2014 and at March 31, 2015, the 2013 Warrants were exercisable at $7.04 per share with approximately 0.6 million warrants outstanding. The 2013 Warrants have a five-year term.

In February 2015, the Company completed the sale of 2.5 million shares of its common stock and the issuance of warrants to purchase 1.1 million common shares (the "2015 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $2.6 million, with net cash proceeds after related expenses from this transaction of $2.5 million. Of those proceeds, the Company allocated an estimated fair value of $0.8 million to the 2015 Warrants. At March 31, 2015, the 2015 Warrants were exercisable at $1.38 per share with approximately 1.1 million warrants outstanding. The 2015 Warrants have a five-year term.

The proceeds allocated to the 2012 Warrants, 2013 Warrants and 2015 Warrants (the "Warrants") were initially classified as derivative instrument liabilities that are subject to mark-to-market adjustments each period. As a result, for the three months ended March 31, 2015, the Company recorded pre-tax derivative instrument income of $0.2 million. The fair value of the Warrants totaled $0.8 million at March 31, 2015. Management expects that the warrants outstanding at March 31, 2015 will either be exercised or expire worthless. The fair value of the Warrants at March 31, 2015 was determined by using an option pricing model assuming the following:

	2015 Warrants	2013 Warrants	2012 Warrants
Expected volatility	89.08%	90.64%	76.58%
Risk-free interest rates	1.31%	1.01%	0.03%
Expected life (in years)	4.88	3.58	0.17

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Delcath's management, with the participation of its Interim Chief Executive Officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) of the Exchange Act). Based on that evaluation, the Company's Interim Chief Executive Officer concluded that Delcath's disclosure controls and procedures as of March 31, 2015 (the end of the period covered by this Quarterly Report on Form 10-Q), have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in the Company's reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including the Company's Interim Chief Executive Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There was no change in our internal control over financial reporting that occurred during the quarter ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

In re Delcath Systems, Inc. Securities Litigation, United States District Court for the Southern District of New York (Case No. 13-cv-3116)

On May 8, 2013, a purported stockholder of the Company filed a putative class action complaint in the United States District Court for the Southern District of New York, captioned Bryan Green, individually and on behalf of all others similar situated, v. Delcath Systems, Inc., et al. ("Green"), Case No. 1:13-cv-03116-LGS. On June 14, 2013, a substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Joseph Connico, individually and on behalf of all others similarly situated, v. Delcath Systems, Inc., et al. ("Connico"), Case No. 1:13-cv-04131-LGS.

At a hearing on August 2, 2013, the Court consolidated the Green and Connico actions under the caption In re Delcath Systems, Inc. Securities Litigation, No. 13-cv-3116, appointed Lead Plaintiff, Delcath Investor Group, and approved Pomerantz Grossman Hufford Dahlstrom & Gross LLP as Lead Plaintiff's choice of counsel.

On September 18, 2013, Lead Plaintiff filed a consolidated amended complaint, naming the Company and Eamonn P. Hobbs as defendants (the "Defendants"). The consolidated amended complaint asserts that Defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by allegedly making false and misleading statements or omissions regarding the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma in the liver. The putative class period alleged in the amended complaint is April 21, 2010 through and including September 13, 2013. Lead Plaintiff seeks compensatory damages, equitable relief, and reasonable attorneys' fees, expert fees and other costs. On October 31, 2013, Defendants filed their motion to dismiss, which was subsequently denied on June 27, 2014. On July 25, 2014, Defendants filed their respective answers to Lead Plaintiff's consolidated amended complaint. On July 29, 2014, the Court held a scheduling conference setting forth a case management plan. The parties are proceeding with discovery. On October 15, 2014, Lead Plaintiff served Defendants with a Motion for Class Certification to which Defendants served an opposition on December 16, 2014. On February 4, 2015, Lead Plaintiff served Defendants with a reply in support of the Motion for Class Certification and the parties filed all class certification pleadings with the Court. The parties have agreed to a settlement in principle subject to the Court's approval.

The Company believes that the In re Delcath Systems, Inc. Securities Litigation action lacks merit and to the extent the settlement does not become final intends to defend the case vigorously.

In re Delcath Systems, Inc. Derivative Shareholder Litigation, United States District Court for the Southern District of New York (Lead Case No. 1:13-cv-03494-LGS)

On May 23, 2013, purported stockholders of the Company filed a shareholder derivative lawsuit in the United States District Court for the Southern District of New York, captioned Vincent J. Orlando and Carol Orlando, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Orlando"), Case No. 1:13-cv-03494-LGS. On June 11, 2013, a substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Howard Warsett, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Warsett"), Case No. 1:13-cv-04002-LGS. On July 19, 2013, another substantially similar complaint was filed in the United States District Court for the Southern District of New York, captioned Patricia Griesi, derivative on behalf of nominal defendant Delcath Systems, Inc. v. Harold S. Koplewicz, et al. ("Griesi"), Case No. 13 cv 5024. In all three cases, Harold S. Koplewicz, Laura A. Brege, Tasos G. Konidaris, Eamonn P. Hobbs, Douglas G. Watson, Laura A. Philips, Roger G. Stoll, and Gabriel Leung were named as defendants (the"Individual Defendants"), and the Company

was named as a nominal defendant.

All three complaints assert claims for breach of fiduciary duty for disseminating false and misleading information, breach of fiduciary duty for failing to properly oversee and manage the company, and gross mismanagement for making false and misleading statements or failing to disclose material information regarding (i) the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma, and (ii) the status of the Company's manufacturing facilities. In addition, the Orlando complaint further asserts claims for contribution and indemnification, abuse of control, and waste of corporate assets, while the Warsett complaint asserts an additional claim for unjust enrichment. The Griesi complaint also asserts additional claims for breach of fiduciary duties for failing to maintain internal controls, unjust enrichment, abuse of control, and violations of Section 14(a) of the Securities Exchange Act of 1934. The relevant time period alleged in the Orlando action is April 21, 2010 through the present, and the relevant time period alleged in the Warsett action is April 10, 2010 through the present. The relevant time period alleged in Griesi is April 21, 2010 through May 2, 2013. The Orlando, Warsett, and Griesi plaintiffs seek damages as well as reasonable costs and attorneys' fees. The Griesi plaintiffs also seek corporate governance reforms and improvements and restitution.

On June 25, 2013, the Court consolidated the Orlando and Warsett actions with the caption In re Delcath Systems, Inc. Derivative Shareholder Litigation, Lead Case No. 1:13-cv-03494-LGS ("Consolidated Derivative Case"). On August 1, 2013, the Court consolidated the Griesi action under the caption In re Delcath Systems, Inc. Derivative Shareholder Litigation, Lead Case No. 1:13-cv-03494-LGS. At a hearing on August 2, 2013, the Court entered an order approving Federman & Sherwood as lead counsel. The Court stayed the Consolidated Derivative Case, pending resolution of an anticipated motion to dismiss in In re Delcath Systems, Inc. Securities Litigation, United States District Court for the Southern District of New York, No. 13-cv-3116.

On September 12, 2014, Plaintiffs Vincent Orlando and Carol Orlando filed a Verified Amended Consolidated Shareholder Derivative Complaint (the "Amended Complaint") in the Consolidated Derivative Case. The Amended Complaint is brought against the Individual Defendants, and names the Company as a nominal defendant (collectively, the "Defendants"). The Amended Complaint alleges breaches of fiduciary duty against the Individual Defendants for disseminating false and misleading information and for failing to properly oversee and manage the company. In addition, the Amended Complaint alleges claims for gross mismanagement, contribution and indemnification, abuse of control, and waste of corporate assets. The relevant time period alleged in the Amended Complaint is April 21, 2010 through the present. The Plaintiffs in the Amended Complaint seek damages as well as reasonable costs and attorneys' fees. On October 27, 2014, Defendants served Plaintiffs with their Motion to Dismiss the Amended Complaint and the motion is fully briefed. The parties have requested the Court hold the motion in abeyance in order to give the parties the opportunity to explore a potential settlement.

The Individual Defendants in the Consolidated Derivative Case deny any wrongdoing, believe the claims are baseless, and will defend accordingly.

Howard D. Weinstein, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al., Supreme Court of the State of New York County of New York (Case No. 652030/2013)

On June 7, 2013, a purported stockholder of the Company filed a shareholder derivative lawsuit in the Supreme Court of the State of New York County of New York, captioned Howard D. Weinstein, derivatively on behalf of Delcath Systems, Inc. v. Harold S. Koplewicz, et al., ("Weinstein") Case No. 652030/2013. The action named Harold S. Koplewicz, Laura A. Brege, Tasos G. Konidaris, Eamonn P. Hobbs, Douglas G. Watson, Laura A. Philips, Roger G. Stoll, and Gabriel Leung as individual defendants (the "Individual Defendants"), as well as the Company, as a nominal defendant.

The complaint asserts claims for breach of fiduciary duty for disseminating false and misleading information, breach of fiduciary duty for failing to properly oversee and manage the company, gross mismanagement, contribution and indemnification, abuse of control, and waste of corporate assets in connection with allegations that the Individual Defendants made false and misleading statements or failed to disclose material information regarding (i) the Company's New Drug Application for its Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), for the treatment of patients with unresectable metastatic ocular melanoma, and (ii) the status of the Company's manufacturing facilities. The relevant time period alleged is April 21, 2010 through the present. The plaintiff seeks damages, as well as reasonable costs and attorneys' fees.

In July 2014, the parties in the Weinstein matter agreed to stipulate to stay the proceeding until the federal district court rules on the anticipated motion to dismiss in In re Delcath Systems, Inc. Derivative Shareholder Litigation, United States District Court for the Southern District of New York (Lead Case No. 1:13-cv-03494-LGS).

The Individual Defendants in the Weinstein matter deny any wrongdoing, believe the claims are baseless, and will defend accordingly.

Item 1A. Risk Factors

Delcath's 2014 Annual Report on Form 10-K, in Part 1 – Item 1A. "Risk Factors," contains a detailed discussion of factors that could materially adversely affect our business, operating results and/or financial condition. There have been no material changes in these risk factors since such disclosure.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not Applicable.

Item 3. Defaults upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures
Not Applicable.

Item 5. Other Information
Not Applicable.

Item 6. Exhibits

Exhibit No.		Description
10.1	(1)	Agreement of Lease dated February 5, 2010 and Lease Modification, Extension and Additional Space Agreement dated September 27, 2010
10.2	(2)	Sublease Agreement between Delcath Systems, Inc. and SLG 810 Seventh Lessee LLC, dated May 22, 2014
10.3	(3)	Sublease Agreement between Delcath Systems, Inc. and ICV Partners, LLC dated August 18, 2014
10.4	(3)	License Agreement between Delcath Systems, Inc. and Dresdner Kleinwort Group Holdings, LLC dated September 23, 2014
31.1	**	Certification by Principal Executive Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	**	Certification by Principal Financial Officer Pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	***	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document
101.LAB		XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

** Filed herewith.

*** Furnished herewith.

(1) Filed as an Exhibit to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed with the SEC on May 5, 2010 and incorporated herein by reference.

(2) Filed as an Exhibit to our Current Report on Form 8-K filed with the SEC on May 28, 2014 and incorporated herein by reference.

(3) Filed as an Exhibit to our Current Report on Form 8-K filed with the SEC on September 30, 2014 and incorporated herein by reference.

DELCATH SYSTEMS, INC.

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 thereunto duly authorized.

May 6, 2015 DELCATH SYSTEMS, INC.
(Registrant)

/s/Jennifer K. Simpson
Jennifer K. Simpson
Interim President and Chief Executive Officer
(Principal Executive Officer)

DELCATH SYSTEMS, INC.

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