DELCATH SYSTEMS, INC.
Form 10-Q
May 04, 2016

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, 2016

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 o (Do not check if a smaller reporting company) Smaller reporting company x

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 4, 2016, 24,118,491 shares of the Company's common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

Table of Contents

DELCATH SYSTEMS, INC.

Condensed Consolidated Balance Sheets

(in thousands, except share data)

	March 31, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 9,545	$ 12,607
Accounts receivables, net	197	277
Inventories	835	757
Prepaid expenses and other current assets	880	960
Total current assets	11,457	14,601
Property, plant and equipment, net	1,070	1,132
Total assets	$ 12,527	$ 15,733
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 128	$ 284
Accrued expenses	1,723	2,243
Warrant liability	2,051	3,785
Total current liabilities	3,902	6,312
Other non-current liabilities	767	820
Total liabilities	4,669	7,132
Commitments and Contingencies		
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	—	—
Common stock, $.01 par value; 170,000,000 shares authorized; 24,696,248 and 22,341,574 shares issued and 24,118,491 and 21,763,817 shares outstanding at March 31, 2016 and December 31, 2015, respectively	247	223
Additional paid-in capital	270,692	269,654
Accumulated deficit	(263,030)	(261,217)
Treasury stock, at cost; 1,757 shares at March 31, 2016 and December 31, 2015, respectively	(51)	(51)
Accumulated other comprehensive income	—	(8)
Total stockholders' equity	7,858	8,601
Total liabilities and stockholders' equity	$ 12,527	$ 15,733

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,	
	2016	2015
Revenue	$370	$444
Cost of goods sold	(111)	(133)
Gross profit	259	311
Operating expenses:		
Selling, general and administrative	2,377	3,040
Research and development	1,344	979
Total operating expenses	3,721	4,019
Operating loss	(3,462)	(3,708)
Change in fair value of the warrant liability, net	1,672	209
Other income (expense)	(23)	11
Net loss	$(1,813)	$(3,488)
Other comprehensive income (loss):		
Foreign currency translation adjustments	8	(14)
Comprehensive loss	$(1,805)	$(3,502)
Common share data:		
Basic and diluted loss per common share	$(0.08)	$(0.32)
Weighted average number of basic and diluted common shares outstanding	23,288,697	10,857,142

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,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(1,813)	$(3,488)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	95	102
Restricted stock compensation expense	138	22
Depreciation expense	87	196
Warrant liability fair value adjustment	(1,672)	(209)
Non-cash interest income	(2)	(1)
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses and other assets	86	(14)
Decrease (increase) in accounts receivable	84	(156)
(Increase) decrease in inventories	(71)	65
Decrease in accounts payable and accrued expenses	(696)	(877)
Decrease in other non-current liabilities	(53)	(54)
Net cash used in operating activities	(3,817)	(4,414)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(15)	(45)
Proceeds from sales of property, plant and equipment	—	—
Net cash used in investing activities	(15)	(45)
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of warrants	767	2,479
Net cash provided by financing activities	767	2,479
Foreign currency effects on cash and cash equivalents	3	(27)
Net decrease in cash and cash equivalents	(3,062)	(2,007)
Cash and cash equivalents:		
Beginning of period	12,607	20,469
End of period	$9,545	$18,462
Supplemental non-cash activities:		
Fair value of warrants issued	$183	$820
Fair value of warrants exercised	$245	$—

See accompanying Notes to Condensed Consolidated Financial Statements.

5

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") as of and for the three months ended March 31, 2016 and 2015 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, 2015 ("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.

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 of our proprietary product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS). In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT).

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

Liquidity and Operating Matters

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred losses since inception and has accumulated deficit of $263.0 million at March 31, 2016. As shown in the accompanying financial statements during the three months ended March 31, 2016, the Company incurred net losses of $1.8 million and used $3.8 million of cash for its operating activities. These factors among others raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

The Company's existence is dependent upon management's ability to obtain additional funding sources or to enter into strategic alliances. There can be no assurance that the Company's efforts will result in the resolution of the Company's liquidity needs. The accompanying statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

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 third quarter of 2016, 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, 2016 and 2015; 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, 2015. There were no newly adopted policies or significant change in existing policies that occurred during the quarter ended March 31, 2016.

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, 2017, 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 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 does not anticipate that this guidance will materially impact its consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. ASU 2015-11 more closely aligns the measurement of inventory in U.S. GAAP with the measurement of inventory in International Financial Reporting Standards by requiring companies using the first-in, first-out and average costs methods to measure inventory using the lower of cost and net realizable value, where net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years. ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not anticipate that this guidance will materially impact its consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740). ASU 2015-17 requires deferred tax liabilities and assets to be classified as non-current on the consolidated condensed balance sheet. ASU 2015-17 is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years and early application is permitted. ASU 2015-17 may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The Company does not anticipate that this guidance will materially impact its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases, which requires entities to report a right-to-use asset and liability for the obligation to make payments for all leases with the exception of those leases with a term of twelve months or less. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the impact of the pending adoption of ASU 2016-02 on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The standard is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is

permitted. The Company is currently evaluating the impact of the pending adoption of ASU 2016-09 on its consolidated financial statements.

(2) Inventories

Inventories consist of the following:

(in thousands)	March 31, 2016	December 31, 2015
Raw materials	$ 353	$ 360
Work-in-process	326	251
Finished goods	156	146
Total inventory	$ 835	$ 757

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	March 31, 2016	December 31, 2015
Insurance premiums	$ 441	$ 625
Kits for clinical use	238	162
Other[1]	201	173
Total prepaid expenses and other current assets	$ 880	$ 960

[1] Other consists of various prepaid expenses and other current assets, with no individual item accounting for more than 5% at March 31, 2016 and December 31, 2015.

(4) Property, Plant, and Equipment

Property, plant, and equipment consist of the following:

(in thousands)	March 31,	December 31, 2015

	2016	
Buildings and land	$556	$ 556
Enterprise hardware and software	1,522	1,520
Leaseholds	1,326	1,305
Equipment	910	902
Furniture	356	355
Property, plant and equipment, gross	4,670	4,638
Accumulated depreciation	(3,600)	(3,506)
Property, plant and equipment, net	$1,070	$ 1,132

Depreciation expense for the three months ended March 31, 2016 was approximately $0.1 million, as compared to approximately $0.2 million for the same period in 2015.

(5) Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	March 31, 2016	December 31, 2015
Compensation, excluding taxes	$395	$ 692
Professional fees	372	481
Short-term portion of lease restructuring	218	220
Clinical trial expenses	230	219
Other[1]	508	631
Total accrued expenses	$1,723	$ 2,243

[1] Other consists of various accrued expenses, with no individual item accounting for more than 5% of current liabilities at March 31, 2016 and December 31, 2015.

(6) Restructuring Expenses

Beginning in 2013, the Company 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, 2016, there was no reserve on the condensed consolidated balance sheets related to the workforce restructurings as all termination benefits have been paid.

In order to help reduce operating costs and more appropriately align its office space with the reduced size of its workforce, the Company 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") 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, 2016, the total remaining lease restructuring liability for its leased office space was approximately $1.0 million, of which approximately $0.2 million and $0.8 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, 2016:

(in thousands)	Employee Costs	Lease Liability	Total Restructuring Liability
Reserve balance at December 31, 2015	$ 71	$ 1,039	1,110
Charges	—	—	—

Payments/Utilizations	(71)	(54)	(125)
Reserve balance at March 31, 2016	$ —	$ 985	985

(7) Stockholders' Equity
Stock Issuances

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. During the three months ended March 31, 2016, the Company sold an additional 50,000 shares for net proceeds of approximately $17,500. 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, 2016, the Company has approximately $39.9 million remaining under the program subject to market conditions and certain limitations.

Warrants

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 exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At March 31, 2016, 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 “February 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 February 2015 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. At March 31, 2016, the February 2015 Warrants were exercisable at $0.355 per share with approximately 1.1 million warrants outstanding. The February 2015 Warrants have a five-year term.

In July 2015, the Company completed the sale of 9.4 million Units consisting of 9.4 million shares of its common stock, Series A Warrants to purchase up to 7.0 million common shares (“July 2015 Series A Warrants”) and Series B Warrants to purchase Units consisting of up to 9.4 million common shares (“July 2015 Series B Warrants”) and 7.0 million July 2015 Series A Warrants pursuant to an underwriting agreement. The Company received proceeds of $7.0 million, with net cash proceeds after related expenses from this transaction of $6.0 million. Of those proceeds the Company allocated an estimated fair value of $3.4 million to the July 2015 Series A and Series B Warrants. The exercise price of both series of warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and is subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. During the three months ended March 31, 2016, 2.2 million July 2015 Series B Warrants were exercised for net proceeds of approximately $0.8 million. The remaining 7.1 million July 2015 Series B Warrants expired on January 29, 2016 and the remaining liability was credited to Change in the fair value of the warrant liability. As a result of the July 2015 Series B Warrant exercises, an additional 1.7 million Series A Warrants were issued. At March 31, 2016, the July 2015 Series A Warrants were exercisable at $0.355 with approximately 8.7 million warrants outstanding. The July 2015 Series A 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 1,506,250 shares, respectively, have been reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. In June 2015, the total number of shares of Delcath common stock reserved for issuance under the 2009 Stock Incentive Plan was increased by 1,100,000 shares, from 406,250 to 1,506,250 shares, upon a favorable vote by the Company’s stockholders. 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. As of March 31, 2016 there were 114,121 shares available to grant under the 2009 Stock Incentive Plan.

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 and Restricted Stock granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee. Options granted under the Plans expire over varying terms, but not more than ten years from the date of grant.

For the three months ended March 31, 2016 and 2015, the Company recognized compensation expense of approximately $0.1 million relating to stock options granted to employees. There were no stock options awards granted during the three months ended March 31, 2016 or 2015.

For the three months ended March 31, 2016, the Company recognized compensation expense of approximately $0.1 million related to restricted stock granted to employees. For the same period in 2015, the Company recognized compensation expense of approximately $0.02 million. There were 75,000 shares of restricted stock granted during the three months ended March 31, 2016. There were no restricted stock awards granted for the same period in 2015.

(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 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 option pricing models. These models use 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 certain price adjustment provisions and 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 models 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, 2016, the Company recorded pre-tax derivative warrant income of $1.7 million. The resulting derivative warrant liabilities totaled $2.1 million at March 31, 2016. Management expects that the Warrants will either be exercised or expire worthless. The fair value of the Warrants at March 31, 2016 was determined by using option pricing models with the following assumptions:

	July 2015 Series A Warrants	February 2015 Warrants	October 2013 Warrants
Expected volatility	93.81%	94.20%	92.70%

Risk-free interest rates	1.04%	0.96%	0.80%
Expected life (in years)	4.3	3.9	2.5

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, 2016, 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, 2016
Assets				
Money market funds (included in Cash and cash equivalents)	$1,943	$ —	$—	$1,943
Liabilities				
Derivative instrument liabilities	$—	$ —	$2,051	$2,051

For the periods ended March 31, 2016 and 2015, there were no transfers in or out of Level 1, 2 or 3 inputs.

The table below presents the activity within Level 3 of the fair value hierarchy for the three months ended March 31, 2016:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

(in thousands)	Warrant Liability
Balance at December 31, 2015	$ 3,785
Total change in the liability included in earnings	(1,672)
Fair value of warrants issued	183
Fair value of warrants exercised	(245)
Balance at March 31, 2016	$ 2,051

(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.

The following potentially dilutive securities were excluded from the computation of earnings per share as of March 31, 2016 and 2015 because their effects would be anti-dilutive:

	March 31, 2016	2015
Stock options	752,379	274,229
Unvested restricted shares	576,000	28,934
Warrants	10,381,952	1,957,157
Total	11,710,331	2,260,320

(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. During the third quarter of 2015, the Company was notified by the Internal Revenue Service that they will be examining the tax return for calendar year 2013. The effect of the outcome cannot be reasonably estimated as the exam is presently in its initial stages. However, the Company does not expect any material change to its financial statements as a result of this audit. Any proposed adjustments would result in an adjustment to the net operating loss carryforward for which a valuation allowance has been provided against the full amount. The Company has not been audited by the 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) 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.

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, 2015 included in the Company's 2015 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, 2016 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, 2016 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, 2016 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, 2015 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 2015 Annual Report on Form 10-K.

Company Overview

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 of our proprietary product—Melphalan Hydrochloride for Injection for use with the Delcath Hepatic Delivery System (Melphalan/HDS). In Europe, our proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System for Melphalan (CHEMOSAT).

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

Our clinical development program for CHEMOSAT/Melphalan/HDS is comprised of: The FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma, a Global Phase 3 clinical trial that is investigating overall survival in mOM, and a Global Phase 2 clinical trial program investigating Melphalan/HDS with and without sorafenib in HCC and Melphalan/HDS in ICC. Our CDP also includes a commercial registry for CHEMOSAT non-clinical commercial cases performed in Europe and sponsorship of select investigator initiated trials (IITs) in HCC and colorectal cancer liver metastases (mCRC).

The direction and focus of our CDP for CHEMOSAT/Melphalan/HDS is informed by prior clinical development conducted between 2004 and 2010, non-clinical, commercial CHEMOSAT cases performed on approximately150 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 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 six orphan drug designations, including three orphan designations for the use of the drug melphalan for the treatment of patients with mOM, HCC and ICC. 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 the CHEMOSAT system in select markets in the European Union where the prospect of securing adequate reimbursement for the procedure is strongest. In 2015 national reimbursement coverage for CHEMOSAT procedures was awarded in Germany, with coverage levels to be determined by German authorities in mid to late 2016.

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 2015 report, cancer is the second leading cause of death in the United States, with an estimated 589,430 deaths and 1,658,290 new cases diagnosed in 2015. 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) projects that medical expenditures will reach $158 billion by 2020, a 27% increase over 2010 levels. 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 development 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 and the ACS, 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 17%, compared to 68% for all cancers diagnosed in 2004-2010. 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 2015 outlines the treatment options for HCC as follows: "Early stage liver cancer can sometimes be treated successfully with surgery to remove part of the liver (partial hepatectomy); however, only a limited number of patients have sufficient healthy liver tissue for this to be an option. Liver transplantation may be an option for individuals with small tumors who are not candidates for partial hepatectomy. Other treatment options include ablation (tumor destruction) or embolization (blocking blood flow to the tumor). Fewer treatment options exist for patients diagnosed at an advanced stage. Sorafenib (Nexavar®) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery and do not have severe cirrhosis."

ICC is the second most common primary liver tumor and accounts for 3% of all gastrointestinal cancers and 15% of HCC cases diagnosed in the U.S. and Europe annually. Outside of resection, which is the only cure for ICC, there is currently no standard of care (SOC). Base on third party research we believe that 90% of ICC patients are not candidates for surgical resection, and that approximately 20-30% of these may be candidates for certain focal interventions. We estimate that approximately 6,500 ICC patients in the U.S. and Europe annual could be candidates for treatment with Melphalan/HDS, which we believe represents a significant market opportunity. We intend to pursue an orphan drug designation from the FDA for Melphalan/HDS for the treatment of patients with ICC.

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® procedure), 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. Patients treated in both clinical and non-clinical settings have received up to 6 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. In our clinical trials, melphalan hydrochloride for injection is provided to both European and U.S. clinical trial sites.

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

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. Results of this study were published in Annals of Surgical Oncology, a prestigious medical journal in December 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.

Integrated Safety Profile from Prior Phase 3 and Phase 2 Trials

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. An integrated safety population comprised of patients treated during our prior clinical development using early versions of the Melphalan/HDS showed these risks to include grade 3 or 4 bone marrow suppression and febrile neutropenia, as well as risks of hepatic injury, severe hemorrhage, gastrointestinal perforation, stroke, and myocardial infarction in the setting of an incomplete cardiac risk assessment. 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. In 2015, physicians in Europe and the U.S. also presented the results of research that signaled an improved safety profile as well as efficacy in multiple tumor types at several major medical conferences.

Current Clinical Development Program

The focus of our current 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. 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.

FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the FOCUS Trial)

In January 2016, we initiated a new pivotal Phase 3 overall survival (OS) clinical trial in hepatic dominant ocular melanoma. Called the FOCUS Trial, this new global Phase 3 trial will evaluate the safety, efficacy and pharmacokinetic profile of Melphalan/HDS versus best alternative care in 240 patients with hepatic dominant OM. The primary endpoint is a comparison of overall survival between the two study arms. Secondary and exploratory endpoints include progression-free survival, overall response rate and Quality of Life (QoL) measures. In the FOCUS trial's treatment phase, patients randomized to the Melphalan/HDS arm will receive up to six treatments at intervals of six to eight weeks for up to 12 months. Tumor response will be assessed in both study arms every 12 weeks until evidence of hepatic disease progression. For patients progressing to the follow-up phase, disease assessment scans will continue every 12 weeks for up to two years.

The FOCUS Trial will be conducted at leading cancer centers in the United States and Europe. The Moffitt Cancer Center in Tampa, Fla. has been activated as a participating center and Jonathan Zager, M.D., FACS, Professor of Surgery in the Cutaneous Oncology and Sarcoma Departments and a Senior Member at Moffitt Cancer Center, is serving as the trial's principal investigator. John Wayne Cancer Institute in Los Angeles, California; Duke Cancer Institute in Durham, North Carolina; MD Anderson Cancer Center in Houston, Texas; and the University of Maryland’s Greenbaum Cancer Center in Baltimore, Maryland were activated as participating centers in April 2016, and we plan to announce the activation of additional centers throughout 2016. We intend to include approximately 30 leading cancer centers in the United States and Europe in the FOCUS Trial.

The FOCUS Trial is being conducted under a Special Protocol Assessment (SPA) we concluded with the U.S. Food and Drug Administration (FDA) in January 2016. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that, if met, would support the submission for regulatory approval of Melphalan/HDS. The agreement also represents the satisfactory resolution of a substantial number of the FDA's issues in the Complete Response Letter (CRL) issued in September 2013. These issues were related to safety of a previous generation of the Melphalan/HDS device and procedure. Delcath completed the work necessary to satisfy these requirements prior to submitting its request for the SPA agreement.

There currently is no standard of care for the treatment of hepatic dominant ocular melanoma. The Melphalan/HDS has been granted orphan drug status by FDA for treatment of patients with ocular melanoma. Based on the strength of the efficacy data in this disease observed in our prior Phase 3 clinical trial and the reports of an improved safety profile from approximately 150 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 believe that ocular melanoma liver metastases represent a high unmet medical need, and that pursuit of an indication in this disease state represents the fastest path to potential approval of the Melphalan/HDS in the U.S.

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

In 2014 we initiated a new Phase 2 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 we expect to add additional centers in the U.S. in 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. The Company intends 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. 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 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 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 identify further clinical development opportunities, support clinical adoption and reimbursement in Europe. Cancer centers in Germany, the United Kingdom, and the Netherlands are participating in the registry and patient enrollment has begun.

Recent Data Presentations

In September 2015, results from a study conducted by two EU treatment centers on the treatment of patients with liver metastases from ocular melanoma with CHEMOSAT was presented as a poster at the European Cancer Congress (ECCO) annual meeting. The study entitled, "Treating Unresectable Liver Metastases of Uveal Melanoma with (Percutaneous) Isolated Hepatic Perfusion with Melphalan: Results from Two Experienced Centers," by E.M. De Leede, M.C. Burgmans, et al., was a retrospective study conducted by investigators at Leiden University Medical Center (LUMC) and Erasmus Medical Center (EMC) in the Netherlands. Investigators compared patients with uveal (ocular) melanoma liver metastases treated with isolated hepatic perfusion (IHP), an open surgical procedure that can be performed only once, with patients treated with repeatable percutaneous hepatic perfusion (PHP) using the CHEMOSAT system with an aim to treat patients twice with a six week interval. Treatment characteristics,

complications, toxicity, progression free and overall survival of both therapeutic approaches were analyzed. Both IHP and PHP treatments were performed with melphalan.

In the IHP cohort (30 patients treated between March 1999 and April 2009) progression free survival was 6 months and recurrence was mainly in the liver, and overall survival was 10 months. In the PHP cohort (9 patients who received 15 PHP treatments since February 2014), the maximum follow-up period was 14 months. Eight patients are still alive, seven without progression of disease. A decrease in red and white blood cell count and thrombocytes after the procedure was observed, and 3 patients needed blood transfusions or platelet infusion. Treatment was overall well tolerated. Investigators concluded that "percutaneous hepatic perfusion appears to be an effective and safe procedure in selected patients with unresectable liver metastases of colorectal cancer or uveal melanoma and can be repeated."

Also in September 2015, results of two European investigator-sponsored studies with CHEMOSAT for the treatment of liver metastases were presented as posters at the Cardiovascular and Interventional Radiology Society (CIRSE) annual meeting. An investigator-sponsored study entitled "Safety and Efficiency of The Delcath 2nd Generation Filter in Percutaneous Hepatic Perfusion (PHP) with Melphalan for Unresectable Hepatic Metastases of Colorectal Cancer and Uveal Melanoma" conducted at the Leiden University Medical Center (LUMC) by M.C. Burgmans, N. de Leede, et al. analyzed safety and pharmacokinetics of CHEMOSAT. Investigators examined pharmacokinetic blood samples taken at baseline and set intervals during 15 PHP procedures performed with CHEMOSAT on 10 patients. The PHP procedures were performed with a melphalan dose of 3.0 mg/kg. Results showed grade 3 complications (mostly asymptomatic leukocytopenia and thrombocytopenia) in seven patients, and febrile neutropenia with bacterial pharyngitis in one patient. Febrile neutropenia was not seen again in the study after growth factors were instituted in a study protocol amendment. Analysis of the first blood samples showed filter efficiency of 93%. Investigators concluded that the efficiency of the Delcath 2nd Generation Filter was very high, and that PHP with the filter was associated with no mortality and acceptable morbidity consistent with commercial use in Europe.

Another study, entitled "Lessons and Early Results from the Largest Single Centre Experience in Europe of Treating Ocular Melanoma Liver Metastases with Chemosaturation via Percutaneous Hepatic Perfusion" and conducted at Southampton University in the United Kingdom by G. Hickson, I. Wilson, B. Steadman, et al., reported results from a retrospective analysis of mortality, morbidity, intra-procedural imaging and complication data on 22 consecutive patients who were planned for PHP treatment over a 30-month period. Of the 20 patients who were able to receive treatment, 11 patients remained alive after a median of 280 days, with one complete response ongoing at more than one year post-treatment. Nine deaths from disease progression occurred after a median of 264 days from the first procedure. A complete imaging response in the liver was observed in two patients (10%), 13 patients (65%) had a partial liver response and two patients (10%) had stable disease for more than three months. Investigators concluded that "PHP is an effective palliative treatment in a bleak disease with an acceptable side-effect profile."

In November 2015 we announced that data from three studies supporting treatment for liver metastases with CHEMOSAT were presented at the European Association of Dermato Oncology (EADO) annual congress, which was held in Marseille, France, October 28-31, 2015.

Details of the presentations are as follows:

Liver Directed Treatment Of Metastatic Uveal Melanoma By Chemosaturation Via Percutaneous Hepatic Perfusion – A Single Centre Experience, Southampton University (United Kingdom), presented by lead author Dr. Ioannis Karydis. Researchers conducted a retrospective evaluation of 20 patients treated with CHEMOSAT over 3 years, analyzing survival, tumor response, time to progression and treatment related adverse events. Eighteen patients were able to receive treatment, and 17 of these were evaluable for study purposes. Results showed that ten patients remained alive after median 256 days, with one complete response (6%), four partial responses (24%), and eleven (65%) patients with stable disease for greater than 90 days. Progression free survival for patients who had progressed was 181 days at the time of data cut off, and six patients were alive for greater than one year following their first treatment. Eight deaths from disease progression occurred at a median of 241 days following first treatment, and there were no treatment related deaths. Treatment overall was well tolerated, and non-hematological adverse events were rare (3). Most common adverse events were transient, mild <grade 2 and included transaminitis (56%) and thrombocytopenia (89%); grade 3 anemia was seen in 4 patients and grade 2-4 neutropenia was seen in 4 patients. Researchers concluded that "PHP can be used safely by an experienced team to deliver liver-directed therapy in selected uveal melanoma patients with high progression free and excellent overall survival."

Treating Unresectable Liver Metastases Of Uveal Melanoma With Percutaneous Hepatic Perfusion With Melphalan, Leiden University Medical Center, Erasmus Cancer Institute (the Netherlands) presented by Dr. Mark Burgmans (Leiden). This is an active two-center Investigator Initiated Phase 2 study that aims to evaluate 20 patients with uveal, or ocular melanoma treated with PHP (CHEMOSAT). Data from the first 11 patients with a maximum follow up period of 16 months were presented. Primary endpoints for the study are response rate (as measured by RECIST criteria) following two treatments at 6-week intervals and the percentage of patients with stable disease. Secondary endpoints are safety, overall survival, hepatic progression free survival, and quality of life. Eighteen treatments have been performed on eleven patients and the maximum follow up is currently sixteen months. Current results are that ten patients remain in follow up, and four are without progression of disease. Four patients experienced grade 3 or 4

toxicities that were managed with blood or platelet transfusions. The researchers concluded that PHP with CHEMOSAT "appears to be an effective and safe procedure in selected patients with unresectable liver metastases of uveal melanoma and can be repeated."

Chemosaturation with Percutaneous Hepatic Perfusion of Melphalan for Hepatic Metastases from Uveal Melanoma: Multiinstitutional Evaluation. This study was presented as a poster by lead author Prof. Thomas Vogl, Frankfurt University Hospital and was a retrospective evaluation of non-resectable hepatic metastases from uveal melanoma in 14 patients treated with CHEMOSAT between 2012 and 2014. Eleven patients who received one to three treatments were evaluated by RECIST criteria; survival time analysis was conducted and complications were recorded. Results showed 4 patients (36%) with a partial response, five (46%) with stable disease, and two (18%) with progressive disease. Survival time ranged between 1.5 months to 23 months, with median overall survival of 6.5 months. Time to progression for the two patients who had progressed was 6.2 months for one patient and 1.6 months for a patient who died after evaluation. Treatment was well tolerated by all 14 patients, with seven experiencing leukopenia, six had thrombocytopenia, and two had neutropenia. Researchers concluded that PHP with CHEMOSAT "has been manifested as a potential treatment for patients with non-resectable hepatic metastases of uveal melanoma." This study was subsequently accepted for presentation at the 2015 Radiology Society of North America (RSNA) annual meeting, held in Chicago, IL from November 29 - December 4, 2015.

Market Access & Commercial Clinical Adoption

European Region

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 European region 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. In March 2016 we announced expansion into Turkey with the activation of the Hacettepe University Clinic in Ankara, Turkey. Hacettepe University Clinic represents the first CHEMOSAT commercial location to be activated outside of the European Union, and we believe the center can serve as an important hub for CHEMOSAT treatment to patients in Turkey and throughout the region. 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.

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 October 2015, we announced that the Institut f r das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, established a national Zusatzentgeld (ZE) reimbursement code for procedures performed with CHEMOSAT in Germany. The ZE diagnostic-related group (DRG) code is a national reimbursement code that augments existing DRG codes until a specific new DRG code can be created. With ZE reimbursement established, hospitals in Germany began to negotiate with insurers to obtain reimbursement rates for CHEMOSAT procedures in February 2016. With the establishment of a ZE code for CHEMOSAT, the procedure is now permanently represented in the DRG catalog in Germany. This decision represents the first national reimbursement mechanism for CHEMOSAT procedures in Europe.

ZE reimbursement will replace the previous Neue Untersuchungs und Behandlungsmethoden (NUB) procedure that required patients in Germany to apply individually for reimbursement of their CHEMOSAT treatment. Until ZE reimbursement rates are negotiated, we expect that Individual Funding Requests (IFRs) will continue to be the

primary reimbursement vehicle in the German market. 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 are being approved.

The establishment of ZE coverage by InEK was made in response to an application made by the German Radiology Society for CHEMOSAT in March 2015 with wide support among medical cancer centers in Germany.

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.

We are supporting 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 continued enrollment in the UK in our Phase 2 HCC and ICC trial in 2016, 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 other markets in the European region will require additional time to secure. We believe that national reimbursement in Germany and publication of our prior Phase 3 trial results will provide support for reimbursement in additional markets such France, Spain and the Netherlands. In the interim period, we are seeking payment through various avenues, including new technology programs.

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 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. Since receiving the 2013 CRL, we have worked to resolve certain clinical, clinical pharmacology, Human Factors and product quality components of the CRL. The 2016 SPA agreement with the FDA represents the satisfactory resolution of a substantial number of these requirements.

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 six 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 an orphan drug designation of the drug melphalan for the treatment of HCC. In July 2015, the FDA granted Delcath an orphan drug designation of the drug melphalan for the treatment of cholangiocarcinoma, which includes ICC.

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 27 Member States of the European Union plus Norway, Iceland and Liechtenstein. 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.

Before we may commercialize a medical device in the EEA, we must comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements entitles a manufacturer to affix a CE conformity mark, without which the products cannot be commercialized in the EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. In April 2011, we obtained authorization to affix a CE Mark for the Generation One CHEMOSAT system and began European commercialization with this version of the CHEMOSAT system in early 2012. In April 2012, the Company 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

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices (i.e., Class I devices which are non-sterile and do not have a measuring function), the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directives. Other devices are subject to a conformity assessment procedure requiring the intervention of a Notified Body, which is an organization designated by a Member State of the EEA to conduct conformity assessments.

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.

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.

Failure to comply with the EEA Member State laws implementing the Medical Devices Directive, with the EU and EEA Member State laws on the promotion of medicinal products or with other applicable regulatory requirements can result in enforcement action by the EEA Member State authorities, which may include any of the following: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, or requiring the manufacturer to issue public warnings, or to conduct a product recall.

The European Commission reviewed the medical devices legislative framework in 2012 with the aim of simplifying it and ensuring a more uniform application of the provisions contained in the medical devices directives across the EEA. We do not believe the adopted regulatory changes will impact our business at this time, though future changes to the medical device legislation may adversely affect our business, financial condition and results of operations or restrict our operations.

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 April 2016, Laura A. Philips, Ph. D., M.B.A and Dennis H. Langer, M.D., J.D. resigned from our Board of Directors; the resignations were effective as of April 3 and April 4, 2016, respectively. The decisions of Drs. Philips and Langer to resign are not the result of any disagreement with the Company on any matter relating to its operations, policies or practices. On April 6, 2016, the Board determined to reduce the size of the Board from seven directors to six directors and the Nominating and Governance Committee of the Board commenced a process to identify one new director as promptly as practicable.

Results of Operations for the three months ended March 31, 2016; Comparisons of Results of Operations for the three months ended March 31, 2015

Three months ended March 31, 2016 and March 31, 2015

Revenue

The Company recorded approximately $0.4 million in revenue related to product sales during the three months ended March 31, 2016. The Company recorded approximately $0.4 million in revenue during the same period of 2015.

Cost of Goods Sold

During both the three months ended March 31, 2016 and 2015, the Company recorded cost of goods sold of approximately $0.1 million. The Company continues to expect 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 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, 2016 and 2015, selling, general and administrative expenses were $2.4 million and $3.0 million, respectively. The $0.6 million improvement is primarily attributable to a reduction in severance accruals related to the ongoing 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.

Research and Development Expenses

For the three month periods ended March 31, 2016 and 2015, research and development expenses increased to $1.3 million from $1.0 million, primarily due to increased investment in clinical development initiatives which are discussed in further detail in the Current Clinical Development Program section above.

Other Income/Expense and Interest Income/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 2015 Annual Report on Form 10-K.

Interest income is from a money market account and interest earned on operating accounts.

Net Loss

The Company recorded a net loss for the three months ended March 31, 2016, of $1.8 million, a decrease of $1.7 million, or 48.0%, compared to a net loss of $3.5 million for the same period in 2015. This decrease in net loss is primarily due to a $0.3 million reduction in operating expenses and a $1.5 million change in the fair value of the warrant liability, a non-cash item.

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, 2016, the Company had cash and cash equivalents totaling $9.5 million, as compared to cash and cash equivalents totaling $12.6 million and $18.5 million at December 31, 2015 and March 31, 2015, respectively. During the three months ended

March 31, 2016 the Company used $3.8 million of cash in its operating activities, which compares to $4.4 million used for operating activities during the comparable period in 2015. The decrease of $0.6 million is primarily driven by a $0.3 million reduction in operating expenses and a reduction in cash payments related to severance, bonus and lease restructuring liabilities. The Company believes that its capital resources are adequate to fund its operating activities through the third quarter of 2016.

Our consolidated financial statements as of March 31, 2016 have been prepared under the assumption that we will continue as a going concern for the next twelve months. We expect to incur significant expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Because Delcath's business does not generate positive cash flow from operating activities, the Company will need to obtain substantial additional capital in order to fund clinical trial research and support development efforts relating to Ocular Melanoma liver metastases, ICC, HCC or other indications, and to fully commercialize the product. The Company believes 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 or on acceptable terms, 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 timing, scope, focus and direction of clinical trials and 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, 2009 and 2013, and "at the market" equity offering programs initiated in 2012 and 2013. 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.

As of March 31, 2016, the Company had two active registration statements. Pursuant to SEC regulations, so long as the Company's public float remains below $75 million, we cannot sell securities from the shelf registration statement which represent more than one third of the market value of our non-affiliated public float during any 12-month period.

In March 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, 2016, Delcath had approximately $39.9 million available under this registration statement subject to market conditions and certain limitations. The Company intends to use this for its "at the market" equity offering program.

In October 2015, the Company filed a registration statement on Form S-3 with the SEC, which was declared effective on October 20, 2015 and allows the Company to offer and sell, from time to time in one or more offerings, up to $77.4 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. This registration statement replaces the shelf registration filed in October 2012. Pursuant to SEC regulations, so long as the Company's public float remains below $75 million, we cannot sell securities from the shelf registration statement which represent more than one third of the market value of our

non-affiliated public float during any 12-month period.

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 2015 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 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 exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. At March 31, 2016, 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 "February 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 February 2015 Warrants. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The exercise price of the warrants is subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. For purposes of these adjustments, dilutive issuances do not include securities issued under existing instruments, under board-approved equity incentive plans or in certain strategic transactions. At March 31, 2016, the February 2015 Warrants were exercisable at $0.355 per share with approximately 1.1 million warrants outstanding. The February 2015 Warrants have a five-year term.

In July 2015, the Company completed the sale of 9.4 million Units consisting of 9.4 million shares of its common stock, Series A Warrants to purchase up to 7.0 million common shares ("July 2015 Series A Warrants") and Series B Warrants to purchase Units consisting of up to 9.4 million common shares ("July 2015 Series B Warrants") and 7.0 million July 2015 Series A Warrants per unit pursuant to an underwriting agreement. The Company received proceeds of $7.0 million, with net cash proceeds after related expenses from this transaction of $6.0 million. Of those proceeds the Company allocated an estimated fair value of $3.4 million to the July 2015 Series A Warrants and Series B Warrants. The exercise price of both series of warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and is subject to anti-dilution adjustments for any issuance of common stock or rights to acquire common stock for consideration per share less than the exercise price of the warrants. During the three months ended March 31, 2016, 2.2 million July 2015 Series B Warrants were exercised for net proceeds of approximately $0.8 million. The remaining 7.1 million July 2015 Series B Warrants expired on January 29, 2016 and the remaining liability was credited to Change in the fair value of the warrant liability. As a result of the July 2015 Series B Warrant exercises, an additional 1.7 million Series A Warrants were issued. At March 31, 2016, the July 2015 Series A Warrants were exercisable at $0.355 with approximately 8.7 million warrants outstanding. The July 2015 Series A Warrants have a five-year term.

The proceeds allocated to the 2013 Warrants, February 2015 Warrants, and the July 2015 Series A 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, 2016, the Company recorded pre-tax derivative instrument income of $1.7 million. The fair value of the Warrants totaled $2.1 million at March 31, 2016.

Management expects that the warrants outstanding at March 31, 2016 will either be exercised or expire worthless. The fair value of the Warrants at March 31, 2016 was determined by using option pricing models assuming the following:

	July 2015 Series A Warrants	February 2015 Warrants	October 2013 Warrants
Expected volatility	93.81%	94.20%	92.70%
Risk-free interest rates	1.04%	0.96%	0.80%
Expected life (in years)	4.3	3.9	2.5

Item 4.Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Delcath's management, with the participation of its 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, 2016 (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 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, 2016 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
Not Applicable.

Item 1A. Risk Factors
Delcath's 2015 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.
32.2	***	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.

31

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 4, 2016 DELCATH SYSTEMS, INC.
(Registrant)

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

DELCATH SYSTEMS, INC.

Exhibit Index

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.
32.2	***	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.