DELCATH SYSTEMS, INC.
Form 10-Q
November 06, 2013

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 September 30, 2013.

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.)

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

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

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

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 o

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

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

As of November 5, 2013, 126,289,659 shares of the Company's common stock, $0.01 par value, were outstanding.

DELCATH SYSTEMS, INC.

Index

		Page
Part I: FINANCIAL INFORMATION		
Item 1.	Condensed Consolidated Financial Statements (Unaudited)	1
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	2
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	12
Item 4.	Controls and Procedures	12
PART II: OTHER INFORMATION		13
Item 1.	Legal Proceedings	13
Item 1A.	Risk Factors	14
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	14
Item 3.	Defaults upon Senior Securities	14
Item 4.	Mine Safety Disclosure	14
Item 5.	Other Information	14
Item 6.	Exhibits	15
SIGNATURES		16

Index
DELCATH SYSTEMS, INC.

PART I:
FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

Index to Financial Statements

	Page
Condensed Consolidated Balance Sheets September 30, 2013 and December 31, 2012	F-1
Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2013 and 2012	F-2
Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2013 and 2012	F-3
Notes to Condensed Consolidated Financial Statements	F-4 – F-13

Index

DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share data)

	September 30, 2013	December 31, 2012
Assets:		
Current assets		
Cash and cash equivalents	$27,735	$23,726
Accounts receivables	111	144
Inventories, net	963	1,105
Prepaid expenses and other current assets	1,200	1,457
Total current assets	30,009	26,432
Property, plant and equipment, net	3,293	4,042
Total assets	$33,302	$30,474
Liabilities and Stockholders' Equity:		
Current liabilities		
Accounts payable	$684	$939
Accrued expenses	3,375	5,790
Warrant liability	863	3,427
Total current liabilities	4,922	10,156
Long term liabilities		
Deferred revenue	7	309
Accrued expenses	490	–
Total long term liabilities	497	309
Commitments and contingencies	–	–
Stockholders' equity		
Preferred stock, $.01 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2013 and December 31, 2012	–	–
Common stock, $.01 par value; 170,000,000 shares authorized; 103,318,021 and 76,849,033 shares issued and 103,289,921 and 76,820,933 outstanding at September 30, 2013 and December 31, 2012, respectively	1,033	768
Additional paid-in capital	250,821	218,063
Accumulated deficit	(224,341)	(198,808)
Treasury stock, at cost; 28,100 shares at September 30, 2013 and December 31, 2012	(51)	(51)
Accumulated other comprehensive income	421	37
Total stockholders' equity	27,883	20,009
Total liabilities and stockholders' equity	$33,302	$30,474

See accompanying notes to condensed consolidated financial statements.

Index

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Product revenue	$72	$39	$152	$146
Other revenues	–	—	300	—
Total revenue	72	39	452	146
Costs of goods sold	(23)	—	(386)	—
Gross profit	49	39	66	146
Operating expenses				
Selling, general and administrative	$4,573	$6,960	$16,919	$21,604
Research and development	2,178	5,254	10,639	20,589
Total operating expenses	6,751	12,214	27,558	42,193
Operating loss	(6,702)	(12,175)	(27,492)	(42,047)
Change in fair value of warrant liability, net	(497)	446	2,345	1,025
Interest income	2	9	18	16
Other expense and interest expense	(9)	(93)	(404)	(204)
Net loss	$(7,206)	$(11,813)	$(25,533)	$(41,210)
Common share data:				
Basic and diluted loss per share	$(0.07)	$(0.18)	$(0.27)	$(0.72)
Weighted average number of basic and diluted common shares outstanding	100,068,998	67,219,224	94,023,834	56,844,697
Other comprehensive income:				
Foreign currency translation adjustments	$15	$87	$384	$83
Comprehensive loss	$(7,191)	$(11,726)	$(25,149)	$(41,127)

See accompanying notes to condensed consolidated financial statements.

Index

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine months ended September 30,	
	2013	2012
Cash flows from operating activities:		
Net loss	$(25,533)	$(41,210)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock option compensation expense	407	2,159
Restricted stock compensation expense	179	763
Depreciation expense	866	1,044
Warrant liability fair value adjustment	(2,345)	(1,025)
Non-cash interest income	(1)	(3)
Changes in assets and liabilities:		
Decrease (increase) in prepaid expenses and other current assets	305	(206)
Decrease (increase) in accounts receivable	36	(941)
Decrease (increase) in inventories	150	(43)
Decrease in accounts payable and accrued expenses	(3,149)	(1,250)
Decrease in deferred revenue and long-term accrued expenses	189	58
Net cash used in operating activities	(28,896)	(40,654)
Cash flows from investing activities:		
Purchase of property, plant, and equipment	(113)	(2,076)
Loss on disposal of equipment	5	—
Proceeds from maturities of short-term investments	—	4,980
Net cash (used in) provided by investing activities	(108)	2,904
Cash flows from financing activities:		
Net proceeds from sale of stock and exercise of stock options and warrants	32,218	40,188
Net cash provided by financing activities	32,218	40,188
Foreign currency effects on cash	795	83
Increase in cash and cash equivalents	4,009	2,521
Cash and cash equivalents at beginning of period	23,726	25,777
Cash and cash equivalents at end of period	$27,735	$28,298
Supplemental non-cash activities:		
Fair value of warrants issued	$—	$3,147
Fair value of warrants exercised	$219	$—

See accompanying notes to condensed consolidated financial statements.

Index
DELCATH SYSTEMS, INC.
Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2013 and 2012

(1) Description of Business

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product, the Delcath Hepatic Delivery System (HDS), is designed to administer high dose chemotherapy and other therapeutic agents to the liver, while controlling the systemic exposure to those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers.

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 for the next twelve months, but anticipates that additional working capital may be required to continue operations. To the extent additional capital is not available when needed, the Company may be forced to abandon some or all of its development and commercialization efforts, which would have a material adverse effect on the prospects of the business. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of product development; uncertainty regarding regulatory approval; technological uncertainty; uncertainty regarding patents and proprietary rights; comprehensive government regulations; limited commercial manufacturing, marketing or sales experience; and dependence on key personnel.

(2) Basis of Condensed Consolidated Financial Statement Presentation

The accompanying 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 instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in the Company’s annual financial statements have been condensed or omitted. The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that impact the amounts reported in the Company’s condensed consolidated financial statements. The condensed consolidated financial statements include the accounts of all entities controlled by Delcath. All significant inter-company accounts and transactions are eliminated. The unaudited interim condensed consolidated financial statements, in the opinion of management, reflect all adjustments (consisting of normal recurring accruals) necessary for a fair statement of the Company’s results of operations, financial position and cash flows for the interim periods ended September 30, 2013 and 2012.

The results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2012, which are contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission (the “SEC”) on March 13, 2013.

(3) Summary of Significant Accounting Policies

Use of Estimates

The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company’s condensed consolidated balance sheets and the amount of expenses reported for each of its periods presented are affected by estimates and assumptions, which are used for, but not limited to, the accounting for derivative instrument liabilities, stock-based compensation, valuation of inventory, income taxes and operating expense accruals. Such

assumptions and estimates are subject to change in the future as additional information becomes available or as circumstances are modified. Actual results could differ from these estimates.

Cash Equivalents and Concentrations of Credit Risk

The Company considers investments with original maturities of three months or less at date of acquisition to be cash equivalents. The Company has deposits that exceed amounts insured by the Federal Deposit Insurance Corporation (FDIC), however, the Company does not consider this a significant concentration of credit risk based on the strength of the financial institutions.

Accounts Receivable

Accounts receivable, principally trade, are generally due within 30 days and are stated at amounts due from customers. As the Company's commercial activities expand, collections and payments from customers will be monitored and a provision for estimated credit losses will be created based upon historical experience and specific customer collection issues that may be identified. At September 30, 2013 there were no accounts receivable determined to be uncollectable.

Inventories

Inventories are valued at the lower of cost or market value using the first-in, first-out method. The reported net value of inventory includes finished saleable products, work-in-process, and raw materials that will be sold or used in future periods. The Company reserves for expired, obsolete, and slow-moving inventory.

Prior to obtaining authorization to affix the CE Mark to its Generation Two Delcath Hepatic CHEMOSAT® Delivery System in April 2012, the Company expensed all of its inventory costs as research and development. Inventory as of September 30, 2013 includes finished goods and components relating to Generation Two Delcath Hepatic CHEMOSAT® Delivery System that have been purchased since April 2012. Therefore, to the extent that materials expensed prior to April 2012 are used in manufacturing finished goods for sale, the Company's cost of goods sold will be adjusted accordingly.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost, less accumulated depreciation. The Company provides for depreciation on a straight line basis over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements will be amortized over the shorter of the lease term or the estimated useful life of the related assets when they are placed into service. Maintenance and repairs are charged to operations as incurred. Expenditures which substantially increase the useful lives of the related assets are capitalized.

Derivative Instrument Liability

The Company accounts for derivative instruments in accordance with Accounting Standards Codification (ASC) 815, which establishes accounting and reporting standards for derivative instruments and hedging activities, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value, regardless of the hedging relationship designation. Accounting for changes in the fair value of the derivative instruments depends on whether the derivatives qualify as hedge relationships and the types of relationships designated are based on the exposures hedged. At September 30, 2013 and 2012, the Company did not have any derivative instruments that were designated as hedges.

Fair Value Measurements

The Company applies ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. ASC 820 applies to reported balances that are required or permitted to be measured at fair value under existing accounting pronouncements; accordingly, the standard does not require any new fair value measurements of reported balances.

ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions about market participant assumptions (unobservable inputs classified within Level 3 of the hierarchy).

- Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.

- Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals.
- Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Deferred Revenue

Deferred revenue on the accompanying condensed consolidated balance sheets includes payment received for product sales to a distributor. When obligations or contingencies remain after the products are shipped, such as training and certifying the treatment centers, revenue is deferred until the obligations or contingencies are satisfied. The Company will recognize the revenue related to product sales when its obligations under the agreement have been satisfied. The Company recognized deferred revenue related to a research and distribution agreement upon the completion of certain requirements under the agreement.

Product Revenue Recognition

Revenue from product sales is generally recognized when all of the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred; product price is fixed or determinable; and collection of the resulting receivable is reasonably assured. The Company recognizes product revenues derived from either direct sales to end hospital customers or indirect sales to distributors when the end hospital customers have completed trainings and are certified to perform patient treatments using our product.

Other Revenue

Other revenue is related to the recognition of previously deferred revenue upon the completion of certain requirements under the Research and Distribution Agreement with Chi-Fu Trading Co., Ltd.

Selling, General and Administrative

Selling, general and administrative costs include personnel costs and related expenses for the Company's sales, marketing, general management and administrative staff, costs related to the Company's commercialization efforts in Europe, professional service fees, professional license, business development and certain general legal activities.

Research and Development

Research and development costs include the costs of materials used for R&D and clinical trials, personnel costs associated with device and pharmaceutical R&D, clinical affairs, medical affairs, medical science liaisons, and regulatory affairs, costs of outside services and applicable indirect costs incurred in the development of the Company's

proprietary drug delivery system. All such costs are charged to expense when incurred.

Stock Based Compensation

The Company accounts for its share-based compensation in accordance with the provisions of ASC 718, which establishes accounting for equity instruments exchanged for employee services and ASC 505-50, which establishes accounting for equity-based payments to non-employees. Under the provisions of ASC 718, share-based compensation is measured at the grant date, based upon the fair value of the award, and is recognized as an expense over the option holders' requisite service period (generally the vesting period of the equity grant). The Company is required to record compensation cost for all share-based payments granted to employees based upon the grant date fair value, estimated in accordance with the provisions of ASC 718. Under the provisions of ASC 505-50, the measurement of compensation costs related to common shares issued to non-employees for services is based on the value of the services provided or the fair value of the shares issued. The measurement of non-employee stock-based compensation is subject to periodic adjustment as the underlying equity instrument vests. The Company expensed its share-based compensation for share-based payments granted under the accelerated method, which treats each vesting tranche as if it were an individual grant.

The Company periodically grants stock options for a fixed number of shares of common stock to its employees, directors and non-employee contractors, with an exercise price greater than or equal to the fair market value of Delcath's common stock at the date of the grant. The Company estimates the fair value of stock options using an option pricing model. Key inputs used to estimate the fair value of stock options include the exercise price of the award, the expected post-vesting option life, the expected volatility of Delcath's stock over the option's expected term, the risk-free interest rate over the option's expected term, and Delcath's expected annual dividend yield. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Recently Adopted Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2013-02 which requires additional disclosures regarding the reporting of reclassifications out of accumulated other comprehensive income. ASU 2013-02 requires an entity to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. This guidance is effective for reporting periods beginning after December 15, 2012. The Company adopted this guidance effective January 1, 2013. The Company's adoption of this standard did not have a material impact on its consolidated financial statements.

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

(4) Inventories

Inventories consist of:

(in thousands)	September 30, 2013	December 31, 2012
Raw materials	$ 241	$ 197
Work-in-process	791	405
Finished goods	263	503
Total inventory, gross	1,295	1,105
Inventory reserves	(332)	–
Total inventory, net	$ 963	$ 1,105

Due to adjustments in the anticipated use of inventory, the Company recorded a $0.3 million reserve for expired, obsolete and slow-moving inventory during the nine months ended September 30, 2013. This cost is included in "Cost of goods sold" in the Condensed Consolidated Statements of Operations.

Index
DELCATH SYSTEMS, INC.
Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2013 and 2012

(5) Property, Plant, and Equipment

Property, plant, and equipment consists of:.

(in thousands)	September 30, 2013	December 31, 2012
Leaseholds	$ 1,742	$ 1,716
Furniture	952	952
Equipment	1,535	1,473
Enterprise hardware and software	2,136	2,141
Buildings and land	603	603
	6,968	6,885
Accumulated depreciation	(3,675)	(2,843)
Total	$ 3,293	$ 4,042

Depreciation expense for the three and nine months ended September 30, 2013 is $0.3 million and $0.9 million, respectively, as compared to $0.3 million and $1.0 million for the same period in 2012.

(6) Restructuring Charges

During the nine months ended September 30, 2013, the Company implemented restructurings of its workforce to better focus the Company's organizational structure, increase efficiency and concentrate financial resources on its clinical development program and European commercialization activity. This resulted in a reduction in the Company's workforce by 29 employees. As a result of termination benefits given to the impacted employees, the Company incurred a total cost of approximately $2.6 million which is reflected on the Condensed Consolidated Statements of Operations in both "Selling, general and administrative expenses" and "Research and development expenses", as appropriate. The $1.7 million in accrued severance expenses at September 30, 2013 is included in both Current Accrued expenses and Long-term Accrued expenses on the Condensed Consolidated Balance Sheets.

(in thousands)	September 30, 2013
Severance and restructuring expenses	$ 2,628
Restructuring expenses paid by September 30, 2013	(883)
Total restructuring expenses accrued as of September 30, 2013	$ 1,745

(7) Assets and Liabilities Measured at Fair Value

Derivative Warrant Liability

The Company allocated part of the proceeds of a private placement and a public offering of the Company's common stock to warrants issued in connection with such transactions. The Company determined that these warrants should be classified as liabilities rather than equity. The valuation of the warrants is determined using an option pricing model. This model uses inputs such as the underlying price of the common stock on the date of valuation, the exercise price of the warrant, volatility, risk free interest rate and expected life of the instrument. 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 model against the fair-value hierarchy criteria and using the lowest level of input as the basis for the fair-value

classification as called for in ASC 820-10-35. There are six inputs: the closing price of the Company's common 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 our historical practice of not granting dividends. The closing price of the Company's common stock would fall under Level 1 of the fair-value hierarchy as it is a quoted price in an active market (ASC 820-10-35-40). The riskless rate of return is a Level 2 input as defined in ASC 820-10-35-48, while the historical volatility is a Level 3 input as defined in ASC 820-10-55-22. Since the lowest level input is a Level 3, the Company determined the warrant derivative liability is most appropriately classified within Level 3 of the fair value hierarchy.

Index
DELCATH SYSTEMS, INC.
Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2013 and 2012

In June 2009, the Company completed the sale of 0.9 million shares of its common stock and the issuance of warrants to purchase approximately 1.0 million common shares (the "2009 Warrants") pursuant to a subscription agreement with a single investor. The Company received gross proceeds of $3.0 million, with net cash proceeds after related expenses from this transaction of approximately $2.7 million. Of those proceeds, the Company allocated an estimated fair value of $2.2 million to the 2009 Warrants. As required by the 2009 Warrant agreement, the exercise price of the warrants was adjusted following the Company's sale of common stock under the "at the market" program during July 2012. At September 30, 2013, the 2009 Warrants were exercisable at $0.29 per share with approximately 1.0 million warrants outstanding. The 2009 Warrants have a five-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3 (333-143280 and 333-159857).

In May 2012, the Company completed the sale of 15.3 million shares of its common stock and the issuance of warrants to purchase 4.6 million common shares (the "2012 Warrants") pursuant to an underwriting agreement. The Company received proceeds of $21.5 million, with net cash proceeds after related expenses from this transaction of approximately $21.1 million. Of those proceeds, the Company allocated an estimated fair value of $3.4 million to the 2012 Warrants. As required by the 2012 Warrant agreement, the exercise price of the warrants was adjusted following the Company's sale of common stock under the "at the market" program during July 2012. At September 30, 2013, the 2012 Warrants were exercisable at $0.29 per share with approximately 4.4 million warrants outstanding. The 2012 Warrants have a three-year term. The shares and warrants were issued pursuant to an effective registration statement on Form S-3 (333-178819).

The fair value of the Warrants totaled $0.9 million at September 30, 2013 and was determined by using an option pricing model assuming the following:

	2012 Warrants		2009 Warrants	
Expected volatility	93.89	%	105.91	%
Risk-free interest rates	0.27	%	0.07	%
Expected life (in years)	1.75		0.75	

For the three and nine months ended September 30, 2013, the Company recorded pre-tax derivative instrument income of $0.5 million and pre-tax derivative instrument expense of $2.3 million, respectively. Management expects that the warrants will either be exercised or expire worthless.

Money Market Funds

The table below presents the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2013, aggregated by the level in the fair value hierarchy within which those measurements fall:

Assets and Liabilities Measured at Fair Value on a Recurring Basis at September 30, 2013
(in thousands)

	Level 1	Level 2	Level 3	Balance at September 30, 2013
Assets				

Money market funds	$1,956	$ —	$—	$ 1,956
Liabilities				
Warrant liability	$—	$ —	$863	$ 863

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
(in thousands)

	Warrant Liability
Beginning balance as of December 31, 2012	$ 3,427
Total change in the liability included in earnings	(2,345)
Fair value of warrants exercised	(219)
Ending balance as of September 30, 2013	$ 863

(8) Stock Options Plans

The Company established the 2004 Stock Incentive Plan and the 2009 Stock Incentive Plan (collectively, the "Plans") under which 3,000,000 and 6,500,000 shares, respectively, were reserved for the issuance of stock options, stock appreciation rights, restricted stock, stock grants and other equity awards. 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. 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 and conditions of each award, the option price and the duration of each award.

Options granted under the Plans vest as determined by the Company's Compensation and Stock Option Committee and expire over varying terms, but not more than ten years from the date of grant. Stock option activity for the nine months ended September 30, 2013 is as follows:

	Stock Option Activity under the Plans			
	Stock Options	Exercise Price per Share	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)
Outstanding at December 31, 2012	4,788,887	$1.23-$15.54	$ 4.79	6.88
Granted	943,020	$0.37-$2.13	2.04	
Forfeited	(1,000,773)	$1.31-$8.50	3.63	
Expired	(20,000)	$1.87	1.87	
Outstanding at September 30, 2013	4,711,134	$0.37-$15.54	$ 4.50	6.30

For the three and nine months ended September 30, 2013, the Company recognized compensation income of approximately $0.2 million and compensation expense of $0.4 million, respectively, relating to stock options granted to employees. The compensation income for the three months ended September 30, is a result of the cancellation of stock options related to the Company's restructuring activities discussed further in Note 6 to the Company's condensed consolidated financial statements contained in the Quarterly Report on Form 10-Q. For the three and nine months ended September 30, 2012, the Company recognized compensation expense of approximately $0.8 million and $2.1 million, respectively, relating to stock options granted to employees.

The Company accounts for stock-based compensation for employees in accordance with the provisions of ASC 718. An option pricing model is used to determine the fair value of stock options awarded to employees on the date of

grant. The Company has expensed its stock-based compensation for share-based payments granted under the ratable method, which treats each vesting tranche as if it were an individual grant.

The Company accounts for stock-based compensation expense for non-employees in accordance with the provisions of ASC 505, which requires using the fair-value method. Under this method, the award is re-measured at each reporting date until the award has vested. The Company estimates the fair value using an option pricing model. The Company has expensed its share-based compensation for non-employees under the ratable method.

Index
DELCATH SYSTEMS, INC.
Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2013 and 2012

The assumptions used in the option pricing model to determine the fair value of stock options awarded to employees are as follows:

	Nine Months Ended September 30,	
	2013	2012
Dividend yield	None	None
Expected volatility	86.16%-93.91%	77.37% - 84.47%
Weighted average volatility	86.37%	79.87%
Risk-free interest rates	0.99%-1.79%	0.78% - 1.49%
Expected life (in years)	6.7	6.0

No dividend yield was assumed because the Company has never paid a cash dividend on its common stock and does not expect to pay dividends in the foreseeable future. Volatilities were developed using the Company's historical volatility. The risk-free interest rate was developed using the U.S. Treasury yield for maturities equal to the expected life of the stock options on the grant date. The expected option term for grants made prior to June 30, 2012 was developed based on the mid-point between the vesting date and the expiration date of each respective grant as permitted under ASC 718. This method of determining the expected holding period was utilized because the Company did not have sufficient historical experience from which to estimate the period. The expected option term for grants made since July 1, 2012 was calculated based on actual historical results.

Restricted stock activity for the nine months ended September 30, 2013 is as follows:

	Restricted Stock Activity under the Plans	
	Restricted Stock	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2012	501,468	$ 3.26
Granted	259,750	0.43
Vested	(317,337)	2.58
Forfeited	(103,986)	4.29
Non-vested at September 30, 2013	339,895	$ 1.41

For the three and nine months ended September 30, 2013, the Company recognized compensation income of $0.1 million and compensation expense of $0.2 million, respectively, relating to restricted stock granted to employees. The compensation income for the three months ended September 30, is a result of the cancellation of restricted stock related to the Company's restructuring activities discussed further in Note 6 to the Company's condensed consolidated financial statements contained in the Quarterly Report on Form 10-Q. For the three and nine months ended September 30, 2012, the Company recognized compensation expense of approximately $0.3 million and $0.8 million, respectively, relating to restricted stock granted to employees.

(9) Common Stock

In December 2012, the Company entered into a Common Stock Purchase Agreement (Purchase Agreement) with Terrapin Opportunity, L.P. (Terrapin) for a committed equity financing facility (CEFF) program. The Purchase Agreement provides that Terrapin is committed to purchase up to $35,000,000 of our common stock over the 24-month term of the Purchase Agreement. During the nine months ended September 30, 2013 the Company sold approximately 5.6 million shares of its common stock through the program. The Company received proceeds of approximately $9.0 million, with net cash proceeds after related expenses from this transaction of approximately $8.9 million. The shares were issued pursuant to registration statement on Form S-3 (333-183675). The net proceeds will be used for general corporate purposes, including, but not limited to, commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures and working capital. In addition to the $9.0 million raised during the nine months ended September 30, 2013, the Company previously raised $2.1 million under the CEFF program. As a result, there was approximately $23.9 million available under this CEFF program as of September 30, 2013.

During the three months ended March 31, 2013, the Company sold approximately 14.2 million shares of its common stock under a sales agreement with Cowen and Company, LLC through an "at the market" equity offering program for proceeds of approximately $20.9 million, with net cash proceeds after related expenses of approximately $20.8 million. There are no shares of common stock of the Company remaining for sale under this sales agreement or registered pursuant to registration statement on Form S-3 (333-165677).

On March 13, 2013, the Company 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 $50,000,000, from time to time, through an "at the market" equity offering program under which Cowen and Company, LLC will act as sales agent. During the three months ended September 30, 2013, the Company sold approximately 6.4 million shares of its common stock under the March 2013 Sales Agreement with Cowen and Company, LLC for proceeds of approximately $2.3 million, with net cash proceeds after related expenses of approximately $2.2 million. The shares were issued pursuant to registration statement 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.

During the nine months ended September 30, 2013, the Company issued 0.2 million shares of its common stock upon the exercise of 2012 Warrants for proceeds of approximately $0.2 million.

(10) Net Loss

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. For the periods presented, basic and diluted net loss per common share are identical. Potentially dilutive securities from stock options, unvested restricted shares and warrants would be antidilutive as the Company incurred a net loss. The number of shares of common stock potentially issuable at September 30, 2013 and 2012 upon exercise or conversion that were not included in the computation of net loss per share totaled 10,490,922 and 10,992,644 shares, respectively.

(11) Taxes

As discussed in Note 11 to the Company's audited financial statements contained in the 2012 Annual Report on Form 10-K, 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 United States, the Republic of Ireland, and certain state jurisdictions. The Company has not been audited by the United States Internal Revenue Service (the "IRS"), international tax authorities, or any states in connection with income taxes. The periods from December 31, 2009 to December 31, 2012 remain open to examination by the IRS and state tax authorities. The periods from December 31, 2011 to December 31, 2012 remain open to examination by the Republic of Ireland. Also note that the federal, state, and international 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.

(12) Legal Proceedings

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

Index
DELCATH SYSTEMS, INC.
Notes to Condensed Consolidated Financial Statements
for the Three and Nine Months Ended September 30, 2013 and 2012

(13) Subsequent Events

During the fourth quarter through November 5, 2013, the Company sold approximately 2.1 million shares of its common stock under the March 2013 Sales Agreement through an “at the market” equity offering program for net proceeds of approximately $0.6 million. The shares were issued pursuant to an effective registration statement on Form S-3 (333-187230). The net proceeds will be used for general corporate purposes, including, but not limited to, funding of the Company’s clinical trials, commercialization of our products, obtaining regulatory approvals, capital expenditures and working capital. As of November 5, 2013, the Company has approximately $46.9 million remaining under the program.

On October 4, 2013, the Company announced that as part of its efforts to increase operating efficiencies, the Company completed a strategic reorganization under which it has eliminated 21 positions, or approximately 33% of its global workforce. In addition to the restructuring charges disclosed in Note 6 to the Company’s condensed consolidated financial statements contained in their Quarterly Report on Form 10-Q, the Company expects to incur an additional approximately $1.4 million in expenses related to this reorganization.

On October 23, 2013, the Company announced the sale of 20,960,000 shares of its common stock and warrants to purchase up to 9,432,000 shares of common stock at a combined price to the public of $0.36 per share and related warrant resulting in approximately $7.5 million in gross proceeds. The transaction settled on October 28, 2013. The warrants are exercisable beginning on the date six months after the date of issuance at an exercise price of $0.44 per share and will expire, unless exercised, on the fifth anniversary of the date of issuance. The net proceeds from the sale of the shares and the related warrants, after deducting the placement agent fees and other estimated offering expenses payable by the Company, will be approximately $6.8 million, which does not include any potential proceeds from the cash exercise of any warrants. The Company intends to use the net proceeds from this offering (including any resulting from the exercise of the warrants, if any) for general corporate purposes, including, but not limited to, funding of its clinical trials, commercialization of its products, obtaining regulatory approvals, capital expenditures and working capital.

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

Index

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, 2012 included in the Company's 2012 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 September 30, 2013 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 September 30, 2013 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 September 30, 2013 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, 2012 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;
- 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 the CHEMOSAT/Delcath Hepatic Delivery System ;
- our ability to successfully commercialize the CHEMOSAT/Delcath Hepatic Delivery System and successfully obtain reimbursement for the procedure and System;
- 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 and Part I, Item 1: Business; and Part II, Item 8: Financial Statements and Supplementary Data of the Company's 2012 Annual Report on Form 10-K.

Index

Delcath Systems, Inc. is a specialty pharmaceutical and medical device company focused on oncology. Our proprietary drug/device combination product, the Delcath Hepatic Delivery System (HDS), is designed to administer high dose chemotherapy and other therapeutic agents to the liver, while controlling the systemic exposure to those agents. The Company's initial focus is on the treatment of primary and metastatic liver cancers.

Leadership Transition

On September 13, 2013 the Company announced that its Board of Directors had implemented a leadership transition plan under which Jennifer Simpson, Ph.D., M.S.N., C.R.N.P., the Company's current Executive Vice President, Global Head of Business Operations, and Graham Miao, Ph.D., M.S., MBA, the Company's current Executive Vice President and Chief Financial Officer, have been appointed to serve as Interim Co-President and Co-Chief Executive Officers. The employment of Eamonn P. Hobbs as President and Chief Executive Officer with the Company was terminated on September 10, 2013; Mr. Hobbs also resigned from the Board of Directors.

In addition to her role as Interim Co-President and Co-Chief Executive Officer, Dr. Simpson shall continue to serve as the Company's Executive Vice President, Global Head of Business Operations. In addition to his role as Interim Co-President and Co-Chief Executive Officer, Dr. Miao shall continue to serve as the Company's Executive Vice President, Chief Financial Officer.

Under the transition plan, Gabriel Leung has been appointed Chairman of the Board. Mr. Leung has been a member of the Board of Directors since 2011. He replaces Dr. Harold Koplewicz as Chairman, who remains a member of the Board of Directors. The Board has also appointed a Transition Committee to assist the Board and management with the leadership transition including the search process for the next President and Chief Executive Officer of the Company. This Committee will also assist the Board in rigorous evaluation of potential strategic options for the Company going forward. The initial members of this Committee are current Board members Mr. Watson, Mr. Stoll, Dr. Koplewicz and Mr. Leung.

Strategic Reorganization

On October 4, 2013 the Company announced that as part of its efforts to increase operating efficiencies, the Company completed a strategic reorganization under which it eliminated 21 positions, or approximately 33% of its global workforce. As a result of these actions and other expense reductions, the Company expects to reduce annual operating costs by approximately $10 million. Most of the savings are expected to come from marketing, administrative expenses and research and development. The Company believes that these actions will help preserve the Company's ability to initiate the strategic objectives currently under evaluation.

About the CHEMOSAT/Melphalan HDS

The CHEMOSAT/ Melphalan HDS system administers concentrated regional chemotherapy to the liver. This “whole organ” therapy is performed by first isolating the circulatory system of the liver, infusing the liver with chemotherapeutic agent, and filtering the blood prior to returning it to the patient. During the procedure, known as percutaneous hepatic perfusion (PHP), three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body’s circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by proprietary filters. The filters reduce the concentration of 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.

Treatment with the CHEMOSAT/Melphalan HDS

Currently there are few effective treatment options for cancers in the liver. Traditional treatment options include surgery, chemotherapy, liver transplant, radiation therapy, interventional radiology techniques, and isolated hepatic perfusion. The most advanced application for which the CHEMOSAT/Melphalan HDS system was evaluated is for the treatment of metastatic melanoma in the liver. During the Company’s clinical trials, the procedure typically took

approximately two to three hours. Patients remained in the intensive care unit overnight for observation after undergoing treatment with the CHEMOSAT/Melphalan HDS system. Treatment with the CHEMOSAT/Melphalan HDS system is a repeatable procedure, and during clinical trials patients received an average of three procedures at approximately four to eight week intervals. A new disposable CHEMOSAT/Melphalan HDS system is used for each treatment.

Risks associated with the CHEMOSAT/Melphalan HDS Procedure

As with many cancer therapies, treatment with CHEMOSAT/Melphalan HDS is associated with toxic side-effects and certain risks, some of which are potentially life-threatening. In clinical trials, the integrated safety population of patients treated with early versions of the CHEMOSAT/Melphalan HDS showed these risks to include: a 4.1% incidence of deaths due to adverse reactions; 4% incidence of stroke; 2% reported incidence of myocardial infarction in the setting of an incomplete cardiac risk assessment; a ≥ 70% incidence of grade 4 bone marrow suppression with a median time of recovery of greater than 1 week; and an 18% incidence of febrile neutropenia, along with the additive risk of hepatic injury, severe hemorrhage, and gastrointestinal perforation. Deaths due to certain adverse reactions did not occur again during the clinical trials following the adoption of related protocol amendments. The trials that comprised this integrated safety population used early versions of the CHEMOSAT/Melphalan HDS system, including the Generation One filter, and did not include use of the Generation Two filter. The Company believes that the risks associated with the procedure are manageable.

Index

Through September 30, 2013, the CHEMOSAT/Melphalan HDS system has been used on over 200 patients through clinical development and early commercial experience in Europe.

Regulatory Status

United States

In the United States, the Melphalan HDS system is subject to regulation as a combination product composed of both a drug product and device product. In August 2012, the Company submitted its New Drug Application (NDA) under Section 505(b)(2) of the Federal Food and 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 it is seeking to ocular melanoma metastatic to the liver for the product under the proposed trade name Melblez Kit. The Company's NDA was accepted for filing by the FDA on October 15, 2012.

On March 18, 2013 the Company supplied certain information in response to an FDA request. Subsequently, on April 3, 2013, the FDA extended its PDUFA goal date to September 13, 2013.

ODAC

On May 2, 2013 the Company announced that the FDA Oncologic Drugs Advisory Committee (ODAC) 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.

A significant portion of FDA's presentation to the ODAC panel was focused on the FDA's assessment of treatment related risks, including the analysis of treatment-related deaths that occurred during clinical trials. Five deaths (4.1%) in the Phase 2 and Phase 3 clinical trials were considered by the treating principal investigators to be treatment-related and resulted from adverse events. Four of these deaths were in the Phase 3 trial and one in the Phase 2 trial. The treatment-related deaths in the pooled PHP population were a consequence of either the PHP procedure; or the direct local effects of melphalan during the procedure, or both.

In the FDA's presentation at ODAC, FDA disagreed with the analysis of procedure related deaths and added three additional deaths, for a total of a 7% percent death rate, in the Phase 2 and Phase 3 programs. Two deaths related to hepatic failure and one death related to myelosuppression, were described.

The FDA also expressed concerns about hypotension (low blood pressure) during the procedure, as well as other procedure related risks. The Company believes that protocol amendments and other procedure refinements instituted during clinical trials or in commercial experience, including changes to the way blood pressure is managed and monitored, may help address these procedure related risks. Collection of adequate safety data on all aspects of the procedure will be a major focus of the clinical trials planned in the Company's Clinical Development Program.

Delcath has posted both the FDA and Company ODAC briefing materials to its website at http://delcath.com/clinical-research/clinical-bibliography.

Complete Response Letter

On September 12, 2013, the FDA issued a complete response letter (CRL) regarding the Company's NDA for Melblez Kit. A CRL is issued by the FDA when the review of a file is completed and questions remain that precludes approval of the NDA in its current form. The FDA comments included 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." In addition to the FDA requirement to conduct an additional clinical trial(s) using the product the Company intends to market, Delcath is evaluating other requirements contained in the letter, and will review potential regulatory paths forward with the FDA. The Company has requested a Type A meeting to clarify components of the CRL. The

Company continues to believe that approval for an indication in ocular melanoma that is metastatic to the liver in the United States would meet a high unmet need.

Index

Europe Economic Area (EEA)

Outside of the United States, the Company's proprietary system to deliver and filter melphalan hydrochloride is marketed as a device under the trade name Delcath Hepatic CHEMOSAT® Delivery System (CHEMOSAT Delivery System for Melphalan). In April 2012, the Company obtained authorization to affix a CE Mark for the Generation Two CHEMOSAT Delivery System for Melphalan. In the EEA, the CHEMOSAT Delivery System for Melphalan is regulated as a Class IIb medical device indicated for the intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) to the liver with additional extracorporeal filtration of the venous blood return. As a Class IIb medical device, 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. The right to affix the CE Mark allows the Company to market and sell the CHEMOSAT System for Melphalan in Europe.

The Company began European commercialization in February 2012 when the first CHEMOSAT procedures performed outside of a clinical trial setting were performed at the European Institute of Oncology in Milan, Italy. Since obtaining the right to affix the CE Mark to the Generation Two CHEMOSAT system, all procedures performed in Europe have been done using the Generation Two system.

With continued economic challenges in certain European markets, the Company's immediate efforts are 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 EEA countries and where progress in securing compelling reimbursement for CHEMOSAT treatments offers the best near-term opportunities. The Company also continues to support clinical adoption of CHEMOSAT in the Netherlands, Italy, Spain and France. Clinical adoption has been slow in France, where compelling reimbursement is difficult to secure. The Company uses a combination of direct and indirect sales channels to market and distribute the CHEMOSAT Delivery System for Melphalan in the EEA. The Company has also utilized a contract field-based team of medical science liaisons (MSL) to educate the medical oncology community in the EU.

During the quarter ended September 30, 2013, CHEMOSAT treatments were performed in Germany (University of Heidelberg), France (Hôpital Saint-André), the United Kingdom (Southampton University Hospital), and the Netherlands (Netherland Cancer Institute). Since launching the CHEMOSAT Delivery System for Melphalan, 14 clinical centers in the EU have used the CHEMOSAT System to treat patients:

Germany
o University of Heidelberg Hospital
o Berlin Charité Hospital
o University Medical Center Göttingen
o Johann Wolfgang Goethe-Universität
o University of Bonn
o Asklepios Clinic Bambek

United Kingdom
o Southampton University Hospital

Italy

o European Institute of Oncology
o Varese University Hospital

The Netherlands
o Netherlands Cancer Institute- Antoni van Leeuwenhoek Hospital

Index

France
o Cancer Institute Gustave Roussy
o Hôpital Saint-André

Spain
o Clinica Rotger Majorca Hospital

Ireland
o University Hospital Galway

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 (HCC), Cholangeocarcinoma, and liver metastases from colorectal cancer (CRC), breast, and cutaneous melanoma.

To support commercialization efforts in the EEA, the Company has established its European Headquarters in Galway, Ireland.

European Reimbursement
A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of compelling reimbursement mechanisms for the procedure in each of the markets we are targeting. In Europe, there is no centralized pan-European medical device reimbursement body. Reimbursement is administered on a regional and national basis, and the Company has engaged a third party reimbursement specialist to support efforts in filing for reimbursement coverage. 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.

Germany
In February 2013, the Company announced that the Institut f r das Entgeltsystem im Krankenhaus (InEk), the German federal reimbursement agency, established a reimbursement pathway for the treatment of patients with liver metastases with the CHEMOSAT System for Melphalan. The Neue Untersuchungs- und Behandlungsmethoden (NUB) Value 4 status given to procedures with the CHEMOSAT System for Melphalan, while not mandating reimbursement, allows participating cancer centers to negotiate reimbursement coverage for the CHEMOSAT procedure with all insurers serving their region. Some of the participating cancer centers in Germany are pursuing reimbursement under the NUB Value 4 scheme, and have begun negotiations with private payers, which may allow hospitals to have the opportunity to submit Individual Funding Applications (IFA) to obtain reimbursement for CHEMOSAT procedure. It is likely that this mechanism will be the key reimbursement vehicle until CHEMOSAT gains permanent mandated reimbursement. In addition, the German Radiology Society has resubmitted its application for ZE (Zusatzentgeld), which is a permanent reimbursement code until a CHEMOSAT specific DRG code can be created. A decision on the ZE application is expected in November 2013. Since a ZE code is dependent on having enough financial data to establish cost averages, it is unlikely that the data is as yet sufficient for this permanent code for CHEMOSAT to be issued at this time. In addition, Delcath supported the resubmission of a NUB application in October with a view to gaining NUB 1 status in February 2014, which would mandate reimbursement for the hospitals that have applied. This form of interim reimbursement is not bound to cost data in the same way as the ZE. Last year, 47 German hospitals applied for NUB, and we anticipate that the majority of Comprehensive Cancer Centers in Germany will submit a NUB application this year. Foremost of these is the National Tumour Center in Heidelberg, a prestigious and highly influential cancer center in Germany which the Company believes will play an important role in support of the reimbursement process and in driving clinical adoption of CHEMOSAT among German physicians.

United Kingdom

In April 2013, interim funding for oncological procedures in the United Kingdom moved away from local Primary Care Trusts (PCTs) to a centralized body of cancer care commissioners. Delcath and its partner centers have identified a Healthcare Resource Groups (HRG) code, which may allow hospitals to be covered for CHEMOSAT procedure related costs. In addition, centers are actively seeking interim funding through the central cancer commissioning board to fund the cost of the CHEMOSAT kit itself. It is important to note that this process has been driven by partner centers and their clinical community, with the centers applying for funding for a limited number of patients with ocular melanoma. The mechanism under which bloc funding is granted is new, and ongoing policy changes in the National Health Service (NHS) make it difficult to predict the likelihood of success in the near term. In parallel, our partner centers are also applying for Individual Funding for their Ocular Melanoma patients. Centers in the United Kingdom are currently waiting for decisions on the funding applications before activating their CHEMOSAT programs. The Company is also engaged with the HRGs that decide on new HRG codes with a view to gaining a dedicated and permanent reimbursement code. At the same time, the National Institute for Clinical Excellence (NICE) may decide to conduct a review of the CHEMOSAT procedure at any time, the outcome of which would determine the long-term reimbursement status. However, the Company does not anticipate an assessment from NICE until a significant number of CHEMOSAT procedures are conducted regularly in the United Kingdom.

Index

Italy

In Italy, the Company identified an existing DRG code that may be used by hospitals to submit for partial reimbursement of the CHEMOSAT device and related procedure. In order to move forward, supplemental new technology payments will be required. This process has taken longer than anticipated due to the unstable political environment in the country that has delayed decisions for extra payments for new technologies. This applies not only to the CHEMOSAT procedure but to all new technologies at the present time.

The Netherlands

The Netherlands is currently reforming its healthcare system, and in the process has moved to a procedure code driven DRG system, referred to as “DOT” in the Netherlands. The process of obtaining a DOT code specific to the CHEMOSAT Delivery System for Melphalan requires that Delcath publishes its Phase 3 data. Following publication, the application for reimbursement will be submitted. In the meantime, the Company is in close contact with the Dutch committee which sanctions new oncological treatments (BOM). Until that time the Company is pursuing the possibility of conducting a limited amount of cases through extraordinary insurance funding at the National Cancer Institute (NKI) in Amsterdam and at the University Hospital in Leiden. The first CHEMOSAT procedures performed in the Netherlands were done at the NKI in Amsterdam in March 2013.

Permanent, compelling reimbursement in remaining EU markets will require additional time to secure. In the interim period, the Company is seeking payment through various avenues, including new technology programs. In France, the Company has revised its strategy and decided not to pursue a multi-center STIC application. STIC is a hybrid of interim funding and clinical study, allowing a new procedure to be assessed over a two-year period on a pre-set number of treatments. The Company believes that the STIC process would be too long and costly, and that direct pursuit of a DRG code represented a better allocation of Company resources in this market. The Company will also present its Phase 3 trial data, once published, to the French healthcare authorities in order to assess the possibility of gaining a DRG code without going through the STIC process. In Ireland, the Company is postponing commercialization efforts until a clear reimbursement pathway is identified.

For many of these countries, publication of the Phase 3 trial manuscript is a key component of the reimbursement process. The Company continues to work with the principal investigators on submission of its Phase 3 and Phase 2 clinical trials for publication. The timing of these submissions will be determined by the principal investigators and the Company looks forward to the submission of the publications.

Other Markets

The Company is currently evaluating commercial opportunities in additional markets on a case by case basis, with the intent of prioritizing available resources on execution of its clinical development program and European commercialization in key markets.

Clinical Development Program

The primary focus of the Company’s Clinical Development Program (CDP) is to obtain U.S. label indications and support clinical adoption in Europe. With the receipt of the CRL from the FDA, the Company is evaluating the regulatory path forward pending FDA’s further guidance. Currently, the Company’s efforts are directed towards initiating a Phase 2 clinical trial to study the CHEMOSAT/Melphalan HDS for the treatment of HCC. In June 2012, the Company amended its Investigational New Drug (IND) application, which permits the use of the Generation Two CHEMOSAT/Melphalan HDS system in the clinical trials planned in its CDP. The Company is also in discussions with key cancer centers in Europe to support certain Investigator Initiated Trials (IIT), which we expect will start in 2014.

About Hepatocellular Carcinoma

HCC is the fifth most common cancer in the world, and is a challenging cancer to treat with only one approved chemotherapy in the United States, Europe, and certain Asian markets. Given an attractive potential market, the role

liver directed therapies may play in primary liver disease, and the positive efficacy signal in the HCC arm of the Company's Phase 2 study, the Company intends to focus its clinical development efforts on securing a labeled indication for CHEMOSAT/Melphalan HDS in HCC.

Index

Phase 2 HCC Cohort

In the Company's multi-arm Phase 2 clinical trial, five patients with HCC were treated with the CHEMOSAT/Melphalan HDS in the primary hepatic malignancy cohort. Among these patients, one patient received 4 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, and we believe constitutes a promising signal that warrants further clinical investigation.

HCC Clinical Development Strategy

On the basis of these encouraging results, the Company intends to initiate a new global clinical trial i